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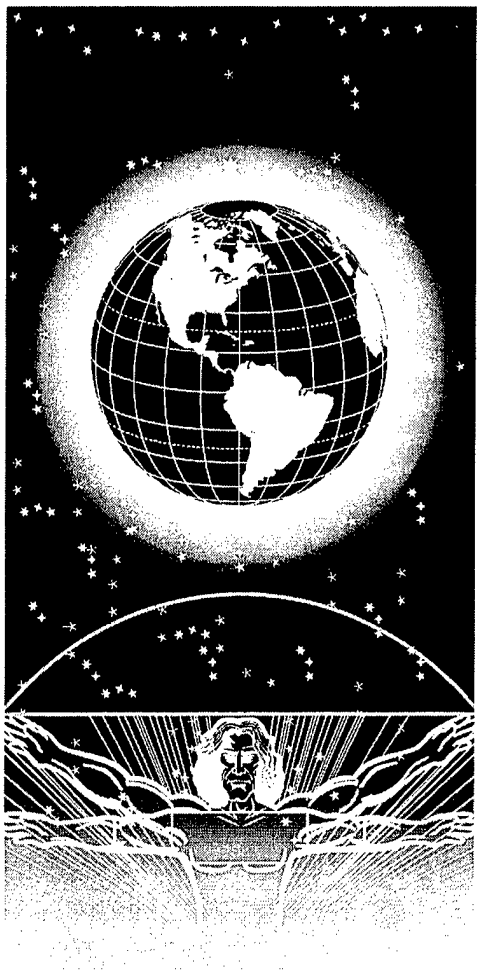

UNITED STATES AIR FORCE RESEARCH LABORATORY

FINAL STATUS REPORT ON MEDICAL ITEMS TESTED AND EVALUATED FOR USE IN THE USAF AEROMEDICAL EVACUATION SYSTEM

Robert Eshelman TSgt, USAF

HUMAN EFFECTIVENESS DIRECTORATE
BIODYNAMICS AND PROTECTION DIVISION
PROTECTION SYSTEMS BRANCH
2504 Gillingham Drive Ste.25
Brooks AFB TX 78235-5104

June 2001

NOTICES

This final technical report was submitted by personnel of the Protective Systems Branch, Biodynamics and Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, AFMC, Brooks Air Force Base, Texas, under job order 7184-56-01.

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The Office of Public Affairs has reviewed this report, and it is releasable to the National Technical Information Service, where it will be available to the general public, including foreign nationals.

This report has been reviewed and is approved for publication.

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14. ABSTRACT
The medical equipment items contained in this report were tested and evaluated primarily for use in the United States Air Force aeromedical evacuation system. The Acceptable/Conditional designations apply only to routine use of a particular piece of equipment in the unique aeromedical evacuation environment of the Department of Defense and are not intended as representative to be relied upon by persons or entities outside the Department of Defense.

15. SUBJECT TERMS
Status Guide, Equipment Guide, Aeromedical Evacuation Equipment

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CONTENTS

PREFACE

This report provides test summaries and recommendations for, and restrictions on, use of medical equipment within the aeromedical evacuation (AE) environment.

The medical equipment listed in this publication has been tested and considered ACCEPTABLE or CONDITIONAL since the publication of the 1996 Status Guide (AL/CF-TR-1995-0171) dated March 1996 and 1990 Status Guide (USAFSAM-TR-90-26) dated December 1990. In the past, Air Force Medical Equipment Development Function (formerly known as Aeromedical Research of Armstrong Laboratory) tested medical equipment for large-bodied cargo aircraft, (C-9A, C-130, and C-141) which were the accepted aeromedical evacuation aircraft. Other aircraft have joined the aeromedical fleet, specifically, the C-21, C-17 and KC-135; testing criteria have been adjusted to accommodate these additional airframes. If the intent is to utilize equipment on smaller-bodied aircraft (less than 75 ft long) or tanker aircraft, please check with 311th HSW/YAML to ensure that it has been evaluated and is safe for use.

Prior to using or purchasing any equipment for use in the aeromedical evacuation environment, please reference the technical reports for these medical devices and/or contact 311th HSW/YAML, Brooks AFB, (DSN 240-2937) for clarification or guidance. No substitute or equal item is authorized unless it has met all airworthiness requirements.

AIR FORCE MEDICAL EQUIPMENT DEVELOPMENT FUNCTION (AFMEDF)
STATUS GUIDE

CATEGORIES

AIR AND OXYGEN
CARDIAC
INCUBATORS
INFUSION
MISCELLANEOUS
POWER
PULSE OXIMETERS
RESPIRATORY
SECURING
SUCTION
VENTILATORS

Equipment Classification. IAW AFI 41-309, Air Force Research Laboratory classifies its equipment into the following categories:

ACCEPTABLE – This equipment is approved for use on large-bodied United States Air Force (USAF) AE aircraft.

CONDITIONAL – This equipment is approved for use on large-bodied USAF AE aircraft ONLY when specific operational restrictions are met.

For more information visit AFMEDF homepage:

https://afml.ft-detrick.af.mil/AFMLO/AFMEDL/afmedl.htm

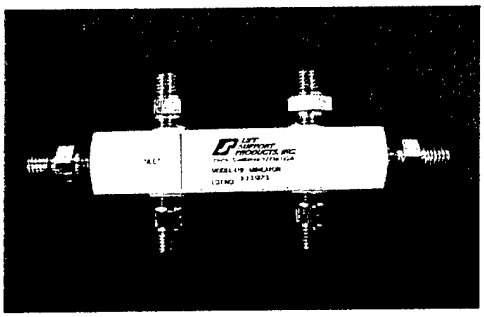
AIR FORCE MEDICAL EQUIPMENT DEVELOPMENT FUNCTION
STATUS GUIDE

AIR & OXYGEN

- LIFE SUPPORT PRODUCTS, MINILATOR
- MINE SAFETY APPLIANCES, CO., MODEL 3000 OXYGEN MONITOR
- MULTI-PURPOSE 50 PSI OXYGEN SYSTEM FOR TRANSPORTING DECOMPRESSION SICKENESS PATIENTS

Product and Manufacturer

LSP MINILATOR



Life Support Products
PO Box 19569
Irvine, CA 92713
(714) 859-0777

Date Evaluated: November 1993

Description:

The LSP Minilator is compact, lightweight, and simple to operate. Given a constant pressure source, the Minilator is a constant flow device that can provide oxygen at flows up to 15 LPM for one to five patients simultaneously. The unit is comprised of an anodized aluminum manifold with check valves and threaded barbed fittings with metered orifices. It can be attached directly to an oxygen regulator capable of delivering 40-90 psi. LSP manufactures other models that provide varying flow, however AFMEDF evaluated Model no. 419-050, an aluminum manifold with five oxygen DISS check valves and five interchangeable 15 LPM orifices. The unit is 1 inch x 6 inches x 7.5 inches and weighs 13.5 ounces.

Summary:

Testing and evaluation concluded the LSP Minilator is CONDITIONAL for use in the aeromedical evacuation environment. The purpose of the study was to validate its air worthiness and find the maximum number of minilators that can be used with the 10 liter PTLOX and C-141 LOX supply systems. It was also established that a minilator could not be used in line with a ventilator. It was determined that a ventilator with a requirement of 50 ±5 psi should not be supported by a gas supply from a hose length exceeding 400 feet. For optimum performance of the ventilator, hose length should not exceed 100 feet. Four people being administered 15 LPM can be supported from one 10 liter PTLOX. Thirty-eight people being administered 15 LPM can be supported from the C-141 liquid oxygen system. Any combination of minilators can be used as long as recommendations in technical report AL/CF-TR-1995-0061 are followed.

Power Requirements: No electrical power. Unit operates using medical grade oxygen pressure.

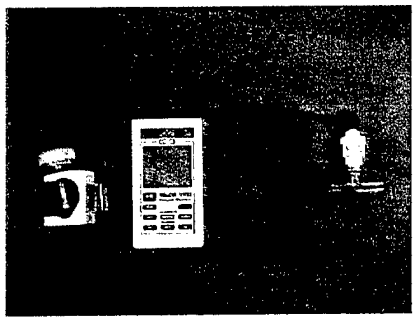
Procurement: Manufacturer

Reference: Technical Report number: AL/CF-TR-1995-0061

Product and Manufacturer

MINE SAFETY APPLIANCES, CO., MODEL 3000 OXYGEN MONITOR

Mine Safety Appliance Company
Pittsburgh, PA 15230
(800) 851-4500



Date Evaluated: June 1997

Description:

The Mine Safety Appliances, Co., Model 3000, Oxygen Monitor is an oxygen monitor designed to provide continuous monitoring of oxygen mixtures. The unit operates on a 9V internal battery. The unit weighs approximately 260 gm or 9.2 oz. and is 3.25 inches W. X 5.98 inches H. X 1.31 inches D.

Summary:

Testing and evaluation concluded the Mine Safety Appliances, Co., Model 3000 Oxygen Monitor is ACCEPTABLE for use on all U.S. Air Force aeromedical evacuation aircraft (including small and large body, fixed and rotary wing) while operating on 9V battery power.

Power Requirements: The unit operates on a 9V internal battery.

Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-1998-0120

Product and Manufacturer

MULTI-PURPOSE 50 PSI OXYGEN SYSTEM FOR TRANSPORTING DECOMPRESSION SICKNESS PATIENTS

AFRL/HEPR
2504 Gillingham Dr., STE 25
Brooks AFB, TX 78235
(DSN) 240-2937

Date Evaluated: May 1995

Description:

The Multipurpose 50 psi Oxygen System was conceived and designed for transportation of a Decompression Sickness (DCS) patient aboard a C-21 Learjet. All components are derived from existing government stock listed items. They include one each: A) Regulator, Chest Mounted, 100% oxygen, Positive Pressure, CRU-79P; B) Low Pressure Oxygen Hose; C) MBU5P or 12P Aviator's mask; D) Connector to attach the O2 Regulator to Mask Hose; E) Hose, O2, Low Pressure; F) AN to 1/8 inch pipe thread nipple; G) 1/8 inch pipe thread to medical oxygen (O2) hose nipple; and H) either Puritan-Bennett or Schrader O2 adapter depending on outlet source.

Summary:

The Multipurpose 50 psi Oxygen System is considered ACCEPTABLE in the aeromedical evacuation environment onboard USAF C-21 Learjets with the following recommendations:

A. Do not use oil or any kind of petroleum products on or around this product.

B. Do not smoke or use combustibles around oxygen equipment.

C. Provide a carrying case to protect the system during handling, such as a USAF helmet bag.

D. Caution needs to be taken not to allow contaminants of any kind to be used on or around the oxygen regulator.

Power Requirements: None

Reference: Technical Report number: AL/CF-TR-1996-0054

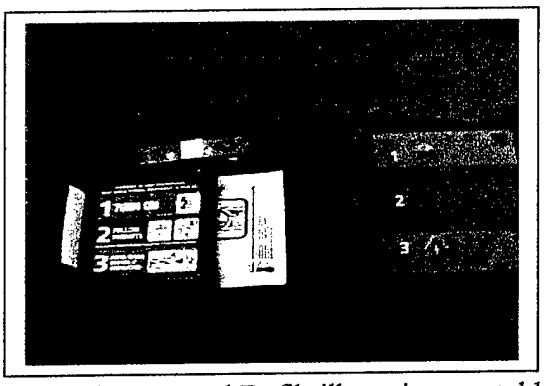
AIR FORCE MEDICAL EQUIPMENT DEVELOPMENT FUNCTION
STATUS GUIDE

CARDIAC

- HEARTSTREAM, INC., MODEL EM SEMI-AUTOMATIC EXTERNAL DEFIBRILLATOR
- HEWLETT-PACKARD CODEMASTER 100 CARDIAC MONITOR/PACEMAKER/DEFIBRILLATOR SYSTEM
- MEDICAL RESEARCH LABORATORIES, INC., 360SLX CARDIAC MONITOR/PACEMAKER/DEFIBRILLATOR SYSTEM
- PHYSIO-CONTROL CORPORATION, LIFEPAK 10 DEFIBRILLATOR/MONITOR/PACER (-47)
- PHYSIO-CONTROL CORPORATION, LIFEPAK 10 DEFIBRILLATOR/MONITOR/PACER (-59)
- PHYSIO-CONTROL CORPORATION, LIFEPAK 500 AUTOMATED EXTERNAL DEFIBRILLATOR
- PROTOCOL SYSTEMS PROPAQ 106 EL PHYSIOLOGIC PATIENT MONITOR
- PROTOCOL SYSTEMS PROPAQ 206 EL ENCORE VITAL SIGNS PATIENT MONITOR
- SPACELABS MEDICAL, INC., ULTRAVIEW MODELS 1030 &1050 PATIENT MONITORS
- SUNSET RESOURCES, ALTERNATING CURRENT INTERFACE UNIT (ACIU)
- ZOLL MEDICAL CORPORATION, PD2000 CARDIAC MONITOR/PACEMAKER/DEFIBRILLATOR SYSTEM
- ZOLL MEDICAL CORPORATION, M SERIES CARDIAC MONITOR/MONOPHASIC AND BIPHASIC DEFIBRILLATOR/PACER/SpO2/AED
- ZOLL MEDICAL CORPORATION, BASE POWERCHARGER ^{4x4}

Product and Manufacturer

HEARTSTREAM MODEL EM SEMI-AUTOMATIC EXTERNAL DEFIBRILLATOR



Agilent Technologies Inc.
3000 Minuteman Rd. Bldg 1
Andover, MA 01810-1099
(800) 934-7372 www.agilent.com

Date Evaluated: June 1998

Description:

The Heartstream, Inc., Model EM Semi-Automatic External Defibrillator is a portable, battery operated, semi-automatic defibrillator. It performs automatic self-tests and displays the results of these tests on a status indicator. The unit is equipped with high resolution, liquid crystal display with back light screen that displays text prompts, patient and event information, and single-lead electrocardiogram (ECG). The unit operates on a disposable 18 VDC lithium battery. The unit weighs approximately 4.34 lbs. (5.8 lbs. with battery, case and defibrillator pads) and is 8.75 inches W. (10 inches with case) X 2.5 inches H. (4.75 inches with case) X 8 inches D. (9.25 inches with case).

Summary:

Testing and evaluation found the Heartstream, Inc., Model EM, Semi-automatic External Defibrillator ACCEPTABLE for use on all U.S. Air Force aeromedical evacuation aircraft while operating on a disposable 18 VDC lithium battery with the recommendations listed below:

A. In certain aircraft such as the C-130/C-141, special training considerations may apply. Considerations include limitations on hearing verbal prompts and the need for auxiliary lighting during periods of low light conditions.

B. On military C-9A aeromedical aircraft, the audible cues could be clearly heard and understood if the ear was within 18 inches of unit without the use of hearing protection.

C. The manufacturer's device offers a patient monitoring electrocardiographic liquid crystal display. According to the manufacturer, the LCD screen is intended only for basic ECG rhythm identification. The frequency response of the monitor screen is not intended to provide the resolution required for diagnostic and ST segment interpretation. Interpretations of the ECG tracing should not be used to guide Advanced Cardiac Life Support interventions.

Power Requirements: The unit operates on a disposable 18 VDC lithium battery.

Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-1998-0121

Product and Manufacturer

HEWLETT-PACKARD CODEMASTER 100 CARDIAC MONITOR/PACEMAKER/DEFIBRILLATOR SYSTEM

Hewlett-Packard Company
1700 South Baker Street
McMinnville, Oregon 97128

Date Evaluated: December 1996

Description:

The CodeMaster 100 is a portable cardiac monitor, defibrillator and pacemaker that offers synchronized defibrillation, electrocardiogram monitoring, noninvasive temporary pacing and pulse oximetry capabilities. The CodeMaster receives power via a rechargeable 12-Volt Ni-Cad battery. The unit's pacer can perform external transcutaneous pacing and can monitor oxygen saturation levels.

Summary:

Testing and evaluation of the CodeMaster 100 System determined it to be CONDITIONAL for use only on large U.S. Air Force aeromedical evacuation aircraft while operating on 115 VAC/60 Hz (Battery Support System) or battery power with the recommendations and restrictions listed below. The CodeMaster 100 System operated within expected parameters when subjected to environmental extremes and simulated cabin altitudes and did not produce a hazard to patient or crew during simulated rapid decompression. The pacer portion of the CodeMaster 100 Pacemaker/Defibrillator is NOT APPROVED for use in the aeromedical evacuation aircraft; however, the inactive pacer portion will survive the flight environment and be an available option for "off the aircraft" use. The following recommendations and operational restrictions accompany the airworthiness approval of the CodeMaster 100 System:

A. Add the following warning to the Operating Instructions and Service Manual: **WARNING**: Restrictions for use on USAF aircraft: The pacing option is NOT to be operational at any time during flight. The M2480B Battery Support System can only be used on 115 VAC/60 Hz.

B. The CodeMaster 100 SpO_2 option exhibited susceptibility during electromagnetic interference testing. ASC/ENAI experts determined that these susceptibility events would be brief (seconds), but that the SpO_2 readings "should not be relied on in critical situations." AFMEDF recommends that the user be alert to potential, temporary, inaccurate SpO_2 readings.

C. After initial electromagnetic interference evaluations, ASC/ENAI, Wright-Patterson AFB, approved the CodeMaster 100 M2475B for use on large-bodied USAF aircraft only. During aircraft taxi, takeoff, and landing (below 10,000 feet) the Hewlett-Packard CodeMaster 100 Defibrillator should not be operated on smaller (C-21 type aircraft) and

rotary-wing aircraft. The CodeMaster 100 Defibrillator has radiated emissions in excess of MIL-STD 461D limits (in the HF, VHF/FM, and VHF/AM frequency bands). Between 137-154 MHz (Vertical Antenna Polarity), the SpO_2 signal display was lost at approximately 15V/M. Between 109-120 MHz and 145-170 MHz (Horizontal Antenna Polarity), the SpO_2 signal display was lost at approximately 15V/M. The emissions should not cause any degradation to flight safety and mission capability when operated as stated above. The pilot and crew should be made aware that the defibrillator system is being operated.

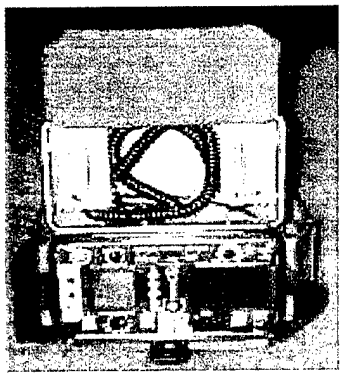
Power Requirements: The CodeMaster receives power via a rechargeable 12-Volt Ni-Cad battery. The M2480B Battery Support System can only be used on 115 VAC/60 Hz.

Procurement: Manufacturer

Reference: Technical Report number: AL/CF-TR-1997-0085

Product and Manufacturer

MEDICAL RESEARCH LABORATORIES, INC., 360SLX CARDIAC MONITOR/PACEMAKER/DEFIBRILLATOR SYSTEM



Medical Research Laboratories, Inc.
1000 Ashbury Drive
Buffalo Grove, IL 60089
Telephone: (708) 520-0300

Date Evaluated: December 1995

Description:

The 360 SLX is a portable cardiac monitor, defibrillator and pacemaker that offers synchronized defibrillation, electrocardiogram monitoring and noninvasive temporary pacing. The defibrillator is capable of delivering up to 360 joules of energy. It may be used in synchronized mode for performance or synchronized cardioversion by using the R-wave of the patient's ECG as a timing reference.

Summary:

Testing and evaluation confirmed the MRL 360 SLX is CONDITIONAL for use on all USAF aeromedical evacuation aircraft while operating on 115 VAC/60 Hz, 28 VDC or battery power. The pacer portion of the 360 SLX Pacemaker/Defibrillator is not approved for use in the aeromedical evacuation aircraft; however, the inactive pacer portion will survive the flight environment and be an available option for "off the aircraft" use.

Power Requirements:

The MRL Rapid Charger/Conditioner is designed to allow the 360SLX to be powered from a 120 VAC/60 Hz source. The 28 Volt DC Converter plugs directly into the 360 SLX and allows the unit to be powered from the aircraft's 28 Volt DC electrical bus. Additionally, the 360 SLX can receive power via a rechargeable 12 Volt, 1.3 Amp or 1.7 Amp hour Ni-Cad battery pack.

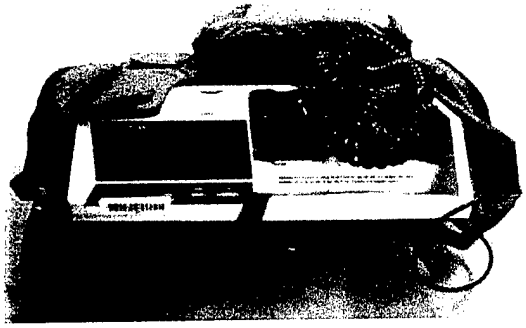
Procurement: Manufacturer

Reference: Technical Report number: AL-CF-BR-TR-1998-0012

Product and Manufacturer

PHYSIO-CONTROL CORPORATION, LIFEPAK 10 DEFIBRILLATOR/MONITOR/PACER (-47)

Physio-Control
11811 Willows Road Northeast
Post Office Box 97006
Redmond, WA 98073-9706
Telephone: (206) 867-4000



Date Evaluated: September 1994

Description:

The LIFEPAK 10-47 is a portable cardiac monitor, defibrillator and pacemaker which offers synchronized defibrillation, electrocardiogram monitoring and the new noninvasive pacing option.

Summary:

The Physio-Control Lifepak 10-47 was found to be CONDITIONAL for use in the aeromedical evacuation environment with the following restrictions:

A. The pacing option is not to be operated at any time during flight.

B. AFMEDF restricted the use of AC Auxiliary Power Supply to 115VAC/60Hz operation only because the LIFEPAK 10-47 exhibits leakage currents in excess of NFPA 99 limits while operating on 115VAC/400 Hz.

C. AFMEDF recommends that the user have a battery in each battery well while operating on 115VAC/60Hz because the battery terminals, which are exposed when the battery wells are empty, exhibit leakage currents in excess of NFPA 99 limits. By ensuring the batteries are in place, potential problems can be avoided.

D. The pacing mode passed all portions of testing while operating on a simulator to include electromagnetic interference (EMI). We certify that the inactive pacer components will not be damaged by the flight environment, however, because of potential differences in EMI characteristics when pacing a human verses the simulator, at time of evaluation we were unable to certify the pacing mode for inflight use.

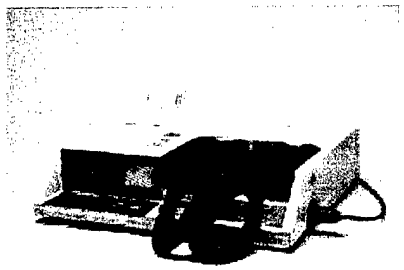
Power Requirements:

The –47 can receive power via any one of three rechargeable nickel-cadmium (Ni-Cd) batteries which are located on the top face of the monitor or by using the Auxiliary Power Module that allows the –47 to be supplied power from a 115 VAC/60 Hz, AC source.

Procurement: Manufacturer

Product and Manufacturer

PHYSIO-CONTROL CORPORATION, LIFEPAK 10 DEFIBRILLATOR/MONITOR/PACER (-59)



Physio-Control
11811 Willows Road Northeast
Post Office Box 97006
Redmond, WA 98073-9706

Telephone: (206) 867-4000

Date Evaluated: September 1994

Description:

The LIFEPAK 10-59 is a portable cardiac monitor, defibrillator and pacemaker which offers synchronized defibrillation, electrocardiogram monitoring, and the new noninvasive pacing option. A Military Auxiliary Power Supply (MAPS), model 806311-07, is designed to allow the –59 to be powered from a 120 VAC/60 Hz or 120 VAC/400 Hz source. Additionally, the –59 can receive power via any one of three rechargeable nickel-cadmium (Ni-Cd) batteries which are located on the top face of the monitor.

Summary:

Testing and evaluation of the defibrillator/monitor portions of the LIFEPAK 10-59 concluded that it is CONDITIONAL for use on all Air Force aeromedical evacuation aircraft while operating on 115VAC/60 Hz or battery power with the following restrictions:

A. The pacing option is not to be operational at any time during flight. Ensure that there is a battery in each well while operating on 115VAC/60 Hz.

B. Do not operate AC Auxiliary Power Supply on 115VAC/400 Hz. The AC Auxiliary Power Supply can only be used on 115VAC/60Hz.

Power Requirements:

A Military Auxiliary Power Supply (MAPS), model 806311-07, is designed to allow the –59 to be powered from a 120 VAC/60 Hz or 120 VAC/400 Hz source. Additionally, the –59 can receive power via any one of three rechargeable nickel-cadmium (Ni-Cd) batteries which are located on the top surface of the monitor.

Procurement: Manufacturer

Reference: Technical Report number: AL/CF-TR-1996-0112

Product and Manufacturer

PHYSIO-CONTROL CORPORATION, LIFEPAK 500 AUTOMATED EXTERNAL DEFIBRILLATOR

Physio-Control
11811 Willows Road Northeast
Post Office Box 97006
Redmond, WA 98073-9706
Telephone: (206) 867-4000

Date Evaluated: June 1998

Description:

The Physio-Control, Inc. model LP500, Automatic External Defibrillator is a portable, battery powered device that provides defibrillation therapy to patients in cardiac crisis. Specific components of the model LP500, Automatic External Defibrillator include: model LP500, automatic external defibrillator basic unit, Quick-Combo pacing/defibrillation/ECG electrodes with REDI-PAK pre-connect system (PN 3008497), LP500 rechargeable sealed lead-acid (LSA) battery pack (PN 3005379), LP500 battery charger (PN 3006535) and LP500 carrying case (PN 3005343). The unit weighs approximately 2.76 kg or 6.1 lb. And is 10.5 inches W. X 4.0 inches H. X 11.6 inches D. The battery charger weighs approximately 0.9 kg or 1.9 lb.

Summary:

1. The test and evaluation of the Physio-Control, Inc. model LP500, Automatic External Defibrillator has been completed. AFMEDF found the Lifepak 500 Automated External Defibrillator to be ACCEPTABLE for use on all U.S. Air Force aeromedical evacuation aircraft operating off 115 VAC/60 Hz power. The following comments and recommendations apply to the Physio-Control, Inc. model LP500, Automatic External Defibrillator:

A. Inform Aircraft Commander that a defibrillator will be in use on-board, they will be notified if defibrillation is to occur due to the possibility of electromagnetic interference with aircraft navigation and communication equipment.

B. In certain aircraft such as the C-130/C-141, special training considerations may apply. Considerations include limitations on hearing verbal prompts and the need for auxiliary lighting during periods of low light conditions.

C. On military C-9A aeromedical aircraft, the audible cues could be clearly heard and understood if the ear was within 18 inches of unit without the use of hearing protection.

Power Requirements:

The unit operates on a rechargeable SLA battery pack. Battery charger operates on AC power (100 to 240 VAC, 50 or 60 Hz).

Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-1998-0023

Product and Manufacturer

PROTOCOL SYSTEMS PROPAQ 106 EL PHYSIOLOGIC PATIENT MONITOR

Protocol Systems, Inc.
8500 S.W. Creekside Place
Beaverton, OR 97008-7107
Telephone: (503) 526-8500

Date Evaluated: August 1995

Description:

The Propaq 106EL is a light weight portable patient monitor capable of monitoring the following: ECG (1 channel: 3-lead); non-invasive blood pressure, (1 channel; cuff); invasive blood pressure, (2 channels); temperature (1 channel: YSI); pulse oximetry (1 channel: SpO_2); CO_2 (1 channel); and respiratory rate. This unit has a printer and HP Connector-Compatible Side Panel. The display in the 106EL is electroluminescent.

Summary:

The test and evaluation of Protocol System's Propaq 106EL, SN: AE00127, and expansion modules, SN's: BD00128, MD00153 and CI00128, has been completed. This unit was found to be CONDITIONAL for use during all phases of flight on large USAF cargo aircraft and in-flight on the C-21 while operating on battery, 115 VAC/60 Hz and 28 VDC in the aeromedical evacuation environment with the following comments and recommendations:

A. AFMEDF recommends that the unit only be stored in environmentally controlled areas because of unit failures during cold storage testing and subsequent conversations with Protocol's engineers concerning temperature sensitive components not designed to meet our extreme storage temperature specifications.

B. Because the carbon dioxide and breath rate sensor is designed to operate within a limited ambient temperature range (50°F to 104°F) and ceased operation during the laboratory's hot operation test (120°F) AFMEDF recommends restricting operational use in extreme hot/cold environments if the carbon dioxide and breath rate sensor is a critical portion of patient monitoring.

C. AFMEDF recommends that personnel be aware of the following potential occurrences during a rapid decompression and be knowledgeable on how to recover the unit. During the laboratory rapid decompression, the 106EL experienced the following: internal "altimeter failure, rate" which renders the carbon dioxide and breath rate sensors inoperative, and (2) cuff "overpressure condition, cycle power" which renders the cuff inoperative. However, neither of these conditions present a safety hazard. Both conditions are correctable when the aircraft returns to cruising altitude or ground. To recover the carbon dioxide and breath rate sensor, simply disconnect and reconnect the sensor from the 106EL. In a cuff overpressure condition, the unit will continue to

operate; however, to recover the cuff channel, simply cycle the power by turning the unit off and then on.

D. AFMEDF evaluated the non-invasive blood pressure (NIBP) option on the 106EL. Our laboratory was unable to "certify" this option for the following reasons: (1) Protocol's NIBP algorithm utilizes a relationship between the blood pressure and the electrocardiogram when determining NIBP, particularly to avoid accepting environmental artifact as pulses, and (2) AFMEDF's current equipment capabilities exclude the ability to synchronize the NIBP and ECG simulators. Without this synchronization during testing, the NIBP values did remain within 10% of the simulator, an accuracy recommended by ECRI as it is comparable to those "obtained by an experienced nurse using a stethoscope and an occluding cuff." Through several portions of testing, the 106EL was intermittently unable to determine the blood pressure. The 106EL would flash errors such as "measurement time out" or "no valid blood pressure found." Protocol's NIBP algorithm experts and AFMEDF engineers have pinpointed these errors as results of the non-synchronized simulators. Without an accurate method using synchronized simulators it is impossible to ensure the accuracy of the NIBP results.

E. The 106EL has many additional features/options to include: HP connectors, multiple power adapters, and defibrillator synchronization. The 106EL is certified for use with the UPA/Style B 503-0054-00 Power Adapter and the Abbott Critical Care invasive pressure sensor, the Transpac IV Single Pressure Kit, part # 4285-05. It is not certified for use with defibrillator synchronization, other power adapters, or HP connectors.

F. After initial electromagnetic interference evaluations, ASC/ENAI, Wright Patterson AFB, approved the 106EL for use on large, USAF cargo aircraft only and recommended that "for smaller air vehicles, . . .the use of the Propaq be evaluated for each platform." Additionally, ASC/ENAI recommends that "the Propaq not be operated during takeoff and landing when used on smaller air vehicles." As a result, AFMEDF and ASC/ENAI evaluated and certified the 106EL for use in-flight on the C-21. The 106EL will require additional evaluations to fly on other small aircraft.

Power Requirements:

DC input power required: 12-28 Volts, 25 watts. The 106EL is powered from an internal, 8 V/6 Amp Hr, sealed lead acid battery or suitable external power source. The Protocol Universal Power Adapter converts 100-120 VAC, 500 mA, 50/60 Hz line voltage to low voltage DC, 16-24 VDC, 25 watts. It operates the 106EL and charges the internal battery. The 106EL can also receive the required input power from Protocol DC power cord. In order to use the power cord on USAF aircraft, a Hubbell Twist-Lock® plug or equivalent is required to be installed.

Procurement: Manufacturer

Reference: Technical Report number: AL/CF-TR-1996-0118

Product and Manufacturer

PROTOCOL SYSTEMS PROPAQ 206 EL ENCORE VITAL SIGNS PATIENT MONITOR

Protocol Systems, Inc.
8500 S.W. Creekside Place
Beaverton, OR 97008-7107
Telephone: (503) 526-8500

Date Evaluated: July 1998

Description:

The unit tested was the Protocol Propaq Encore model 206 EL, SN: DA0006428 with expansion module SN: DC003733. The Propaq Encore expansion module attaches to the monitor and houses additional capabilities. This expansion module was fitted with Printer, Pulse Oximetry, and Capnography CO_2 options. This unit is a lightweight portable patient monitor capable of monitoring: ECG (1 channel: 3-lead); noninvasive blood pressure, (1 channel: cuff); IBP, invasive blood pressure, (2 channels); temperature (2 channels: YSI-400 and 700 series-compatible connectors); pulse oximetry (1 channel: SpO_2); CO_2, (1 channel); and respiratory rate. This unit has a printer and Hewlett-Packard Connector-Compatible Side Panel. The display in the 206 EL is Electroluminescent (EL). With printer/ SpO_2 / CO_2 the dimensions of the unit are as follows: height, 9.65 inches (24.5cm); width, 8.25 in (20.9cm); depth, 7.56 in (19.2 cm); weight, 12.68 lb (5.8 kg).

Summary:

The test and evaluation of Protocol System's Propaq 206EL, SN: DA006428, and expansion module, SN: DC003733 has been completed. This unit, and all 206 ELs with serial numbers higher than EA000225*, was found to be ACCEPTABLE for use during all phases of flight on all USAF aircraft (including small and large body, fixed and rotary wing) while operating on battery, 115 VAC/60 Hz, and 28 VDC in the aeromedical evacuation environment with the following comments and recommendations:

A. Because the carbon dioxide and breath rate sensor ceases operation during the laboratory's hot operation test (120°F), AFMEDF recommends restricting operational use in extreme hot environments if the carbon dioxide and breath rate sensor is a critical portion of patient monitoring.

B. AFMEDF recommends that the 206 EL be mounted such that a crew member is consistently able to monitor the display from a front view because the audible alarms are difficult to hear in a noisy aircraft environment and the visual alarm indicators are difficult to view from the side of the unit. The securing capabilities with the 206 EL proved adequate utilizing litter equipment brackets with litter straps or the Waters Bracket. However, patient connectors and the display limit positioning of the cargo straps and may indicate the need for a more versatile mounting system for the 206 EL.

C. The 206EL has many additional features/options to include: HP connectors, multiple power adapters, and defibrillator synchronization. The HP connector-compatible option makes the Propaq Encore compatible with many Hewlett-Packard sensors and accessories used with the Hewlett-Packard Component Monitoring System. This option was not tested and therefore not approved for use. As the Defibrillator Synchronization feature is designed to operate only with the Physio-Control LifePak 5 and LifePak 6 defibrillators, it was not tested and likewise not aeromedical airworthiness certified. The Propaq Encore is approved for use only with the UPA/Style B 503-0054-00 Power Adapter.

D. Based on prior analysis of Protocol Systems comparison of the Propaq 206 EL with the 202 EL and 204 EL, AFMEDF has concluded that the physiologic patient monitors (with serial numbers higher than EA000225*) will not require additional testing and can also be considered approved for use on all USAF aircraft.

*NOTE: Units with serial numbers lower than EA000225 were certified for operation during all phases of flight only on cargo (large body) USAF aircraft.

Power Requirements:

The 206 EL has an internal, 8 V/6 Amp-hr, sealed gel-type lead-acid battery. Battery life is rated at 3.5-4.5 hours depending on product configuration with a recharge time of 8-12 hours with the instrument on, or 6-8 hours with the instrument off. The unit has an adapter, which converts 100-120 VAC/60 Hz to 16-24 VDC/25 VA: part number 503-0054-00. The unit can also be powered by an external 12-28 VDC source.

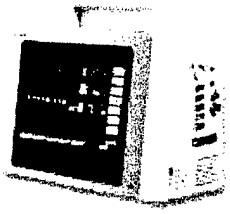
Procurement: Manufacturer

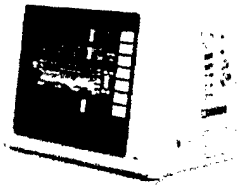
Reference: Technical Report number: AFRL-HE-BR-TR-1998-0053

Product and Manufacturer

SPACELABS MEDICAL, INC., ULTRAVIEW MODELS 1030 &1050 PATIENT MONITORS

SPACELABS MEDICAL INC.
15220 N.E. 40th Street
Redmond, WA 98073-9713
Telephone: (770) 518-8104





Date Evaluated: July 1998

Description:

The Spacelabs Medical, Inc., Ultraview Models 1030 & 1050, patient monitors are lightweight, compact, portable patient care monitoring systems. The Ultraview models provide diagnostic data in the form of 10-Lead ECG, SpO_2, invasive and non-invasive blood pressure, temperature, and cardiac output (not tested). The Ultaview models integrate functional controls by way of touch-screen technology. All input diagnostic data is stored internally for up to 24 hours or printed directly.

Summary:

AFMEDF found the Spacelabs Medical, Inc., Ultaview, Models 1030 & 1050, Patient Monitors to be CONDITIONAL for use on all U.S. Air Force aeromedical evacuation aircraft while operating from 115 VAC/60 Hz and internal battery power. The following recommendations apply:

A. The unit was assessed with the following modes operating, NIBP, IBP, SpO_2, Temp, and ECG. Cardiac Output mode was not assessed per manufacturer decision.

B. Audible alarms are limited in volume intensity with hearing protection on. Crewmembers must rely on visual prompts; which could be viewed with proper placement up to 7 feet away.

C. Problems seen during cold storage evaluation were the unit's inability to recover from exposure to – 40°C within the allotted one hour period. The flat-panel display could not display input diagnostic information needed to diagnose a patient's condition until it had returned to a more liquefied state. AFMEDF engineers suggest refraining from subjecting the unit to environmental temperatures below those outlined in the manufacturer's literature.

D. As with any pulse oximeter, patient movement or vibration of the unit may cause pulse rate and SpO_2 to be erratic and unreadable; therefore, it should be used for trend analysis only.

E. Battery endurance revealed operation time well within manufacturer's specifications. The battery operated the device for approximately 3.1 hours. The unit exceeded manufacturer's specifications regarding recharge times. The unit takes approximately 3

hours to indicate full recharge of the internal batteries, exceeding the 1.5 hours stated in the Owners Manual. Suggest changing manufacturer literature to reflect new recharge times.

Power Requirements: The unit operates on 115 VAC/60 Hz and internal rechargeable battery.

Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-2000-0015

Product and Manufacturer

SUNSET RESOURCES INC., ALTERNATING CURRENT INTERFACE UNIT (ACIU)

Sunset Resources Inc.,
4318 Woodcock Dr., Suite 200
San Antonio, TX 78228

Date Evaluated: May 1996

Description:

The Alternating Current Interface Unit (ACIU) is a portable battery charger/eliminator for use with the Physio-Control LifePak 10 Portable Cardioscope/Defibrillator. The ACIU uses worldwide and aircraft alternating current (AC) power sources converting it to direct current (DC) power. The DC power simultaneously operates the LifePak 10 and charges up to three installed LifePak 10 Nickel-Cadmium (ni-cad or NiCd) battery packs. The ACIU is intended for use in all operational and environmental profiles supported by the LifePak 10. The ACIU is rectangular shaped with dimensions of 9.2 inches L X 7.2 inches W X 3.5 inches H. The unit is constructed of lightweight extruded aluminum and weights 6.8 lbs. The ACIU accepts AC power at 100 to 200 VAC, 50 to 400 Hz.

Summary:

The Alternating Current Interface Unit (ACIU) is considered CONDITIONAL. It operates within expected parameters when subjected to environmental extremes and simulated cabin altitudes, and does not produce a hazard to patient or crew during rapid decompression. The ACIU is restricted to use on **115 VAC/60** Hz power **"ONLY"** due to the increased leakage current levels seen during evaluation of 115 VAC/400 Hz power

Power Requirements: 115 VAC/60 Hz

Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-1996-0055

Product and Manufacturer

ZOLL MEDICAL CORPORATION, PD 2000 CARDIAC MONITOR/PACEMAKER/DEFIBRILLATOR SYSTEM

ZOLL Medical Corporation
32 Second Avenue
Burlington, MA 01803-4420
Telephone: (800) 348-9011

Date Evaluated: September 1997

Description:

The ZOLL Medical Corporation PD 2000 is a portable cardiac monitor, defibrillator and pacemaker that offers synchronized defibrillation, electrocardiogram monitoring, noninvasive temporary pacing, and advisory capability. The defibrillator is capable of delivering up to 360 joules of energy. It may be used in synchronized mode for performance of synchronized cardioversion by using the R-wave of the patient's ECG as a timing reference. The ZOLL PD 2000 uses conventional paddles or disposable, pre-gelled, Multi-Function Electrodes for defibrillation. The PD 2000 is equipped with an advisory function to identify ventricular fibrillation and shockable ventricular tachycardias via an algorithm according to a specification for ventricular fibrillation and wide QRS-complex ventricular tachycardias with a rate greater than 150 beats per minute.

Summary:

AFMEDF found the ZOLL Medical Corporation PD 2000 System to be ACCEPTABLE for use on all U.S. Air Force aeromedical evacuation aircraft while operating on 115 VAC/60Hz or battery power with recommendations listed below:

A. The pacing option is not to be operational at any time during flight. The Power Charger can only be used on 115 VAC/60 Hz. Ensure that there is a battery in the well while operating on 115 VAC/60 Hz.

B. Inform the Aircraft Commander that a cardiac monitor will be in use onboard, and that they will be notified if defibrillation is to occur because of the possibility of electromagnetic interference with aircraft navigation and communication equipment.

Power Requirements:

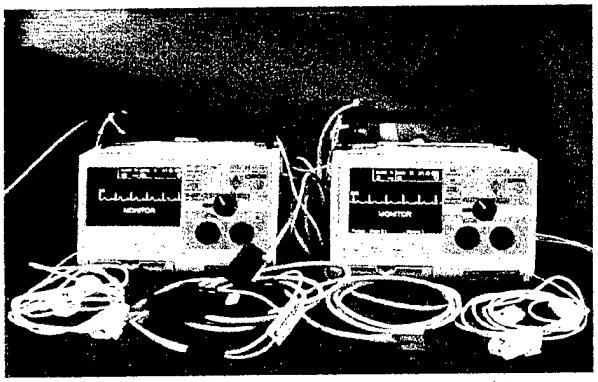
The Power Charger is designed to allow the PD 2000 to be powered from a 120 VAC/60 Hz or 120 VAC/400 Hz source. Additionally, the PD 2000 can receive power via a rechargeable sealed lead-acid battery pack located on the top face of the monitor.

Procurement: Manufacturer

Reference: Technical Report number: AL/CF-TR-1997-0084

Product and Manufacturer

ZOLL MEDICAL CORPORATION, M SERIES CARDIAC MONITOR/MONOPHASIC AND BIPHASIC DEFIBRILLATOR/PACER/SpO2/AED



ZOLL Medical Corporation
32 Second Avenue
Burlington, MA 01803-4420
Telephone: (800) 348-9011

Date Evaluated: September 1999

Description:

The ZOLL M Series devices combine a cardiac defibrillator, ECG display, AED (Automated External Defibrillator), pulse oximetry (SpO_2), advanced monitoring capabilities, cardiac Noninvasive Transcutaneous Pacing (NTP) with communication, data printing and recording capabilities in a single lightweight portable instrument. The devices are powered by either AC mains (115 VAC/60 Hz) or an easily replaced battery pack (ZOLL Smart Battery PD 4410) that is quickly recharged in the M Series device when it is connected to AC mains. The device can operate as an automated external defibrillator with manual capabilities and may be configured to operate in manual advisory or semi-automated modes. Information regarding the units operation, ECG, and other physiological waveforms are displayed on a large 4.5-inch diagonal field emissions display (FED) which provides high contrast and visibility. Self diagnostic tests are performed when the instrument is turned on and the unit is periodically tested during operation.

Summary:

1. The test and evaluation of the ZOLL Medical Corp., M Series, MonoPhasic Cardiac Monitor/Defibrillator/Pacer/ SpO_2/AED (SN: T98I00471) & BiPhasic (SN: T00A08248) Cardiac Monitor/Defibrillator/Pacer/ SpO_2/AED has been completed. AFMEDF found the M Series MonoPhasic and BiPhasic models ACCEPTABLE for use during all phases of flight on all USAF aircraft (including fixed and rotary wing) provided they have been modified IAW EMI report number B00-4 (dated 9 May, 2000) and ZOLL Interim Report (dated 22 May, 2000). Approval includes in-flight operation for transcutaneous pacing on both the MonoPhasic and BiPhasic models. Either model may be used in-flight operating on battery or from 115 VAC/60Hz. WRACC/TIECD engineers at Robins AFB, GA evaluated the explosive atmosphere test data and determined the medical device did not pose an explosive atmosphere hazard. The M Series operated within expected parameters when subjected to environmental extremes and simulated cabin altitudes and did not demonstrate the potential for being a hazard to patients or crews during rapid decompression testing.

2. The following comments and recommendations apply to the M Series MonoPhasic and BiPhasic while in the aeromedical evacuation environment:

   A. In certain aircraft such as the C-130/C-141, special training considerations may apply. Consider limitations due to aircraft ambient noise limiting audio alarms. Audible alarms

were severely degraded while onboard C-130H aircraft due to high ambient noise levels in-flight. The M Series MonoPhasic and BiPhasic should be positioned to allow visual alarm monitoring by aeromedical evacuation crewmembers throughout all phases of flight.

B. On military C-9A aeromedical aircraft, the audible cues could be clearly heard and understood within 6-10 feet of the M Series MonoPhasic and BiPhasic units without the use of hearing protection.

C. No transport case was evaluated. Care needs to be taken during transport to prevent damage to the M Series MonoPhasic and BiPhasic units. However, the manufacturer provided an Xtreme Pack to protect the units from harsh use. AFMEDF found the Xtreme pack useful in preventing damage during rough handling and did not interfere with normal use.

RECOMMENDATIONS

The following recommendations and operational restrictions accompany the airworthiness approval of the M Series:

1. Attach a warning label on the power cord that reads, **"Do not operate on 115 VAC/400 Hz."**

2. Attach a warning label near the battery well that reads, **"Place battery in well before operating from 115 VAC/60Hz."**

3. Inform aircraft commander during pre-mission briefing that the M Series monitor will be used in-flight, and notify the aircraft commander if defibrillation is to occur due to the possibility of electromagnetic interference with aircraft navigation and communication equipment.

4. AFMEDF does not recommend that ZOLL Battery PD4410 or ZOLL Smart Battery PD4410 from the MonoPhasic and BiPhasic units be used with the ZOLL PD 4420 Battery Support System due to manufacturer's warnings about 4410 batteries overheating without special precautions being taken.

Power Requirements:

The devices are powered by either AC mains (115 VAC/60 Hz) or an easily replaced battery pack (ZOLL Smart Battery PD 4410)

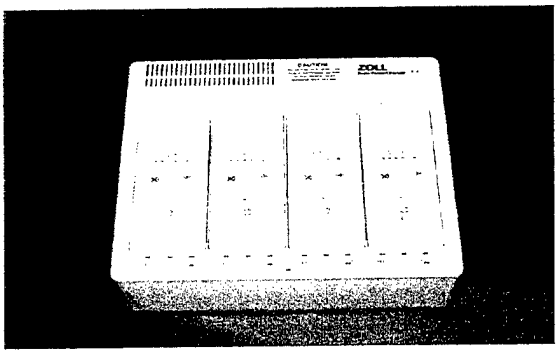
Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-2000-0152

Product and Manufacturer

ZOLL MEDICAL CORPORATION, BASE POWERCHARGER ^{4x4}

ZOLL Medical Corporation
32 Second Avenue
Burlington, MA 01803-4420
Telephone: (800) 348-9011



Date Evaluated: November 2000

Description:

The ZOLL Base PowerCharger ^{4X4} is a battery charger and testing system designed for management of PD 4410 battery packs used in ZOLL Medical Corporations resuscitation devices. The PowerCharger provides four battery charging/testing compartments. Up to four battery packs may be charged or tested in any combination at one time. The ZOLL Base PowerCharger ^{4X4} with Auto Test automatically tests battery capacity with each battery recharge. In addition, the outer case of the PowerCharger ^{4X4} illuminates the **Batt. Ready** indicator when the battery is fully charged and capable of powering a ZOLL M Series MonoPhasic or BiPhasic cardiac monitor for approximately 2.0 hours in monitor mode. Fully charged batteries whose capacity is insufficient to power the devices for this period of time will cause a **Fault** light to illuminate. With Auto Test, the full charging time is complete in 8 hours or less.

Summary:

1. The test and evaluation of the ZOLL Medical Corp., PowerCharger ^{4X4} with Auto Test (Model 8050-0002-30 Military), and PD 4410 rechargeable Smart batteries (model 8004-0103-30) has been completed. AFMEDF found the PowerCharger ^{4X4} ACCEPTABLE for use during all phases of flight on all USAF aircraft (including fixed and rotary wing). The PowerCharger ^{4X4} was also evaluated for compliance with MIL-STD 810F. WRACC/TIECD engineers at Robins AFB, GA evaluated the explosive atmosphere test data and determined the medical device did not pose an explosive atmosphere hazard. The PowerCharger ^{4X4} operated within expected parameters when subjected to environmental extremes and simulated cabin altitudes and did not demonstrate the potential for being a hazard to patients or crews during rapid decompression testing. The engineers at ZOLL Medical Corporation assigned specific military part numbers to the PowerCharger ^{4X4}. The military ^{4X4} Base PowerCharger with AutoTest is PN: 8050-0002-30; the military Smart Battery is PN: 8004-0103-30.

2. The following recommendations apply to the ZOLL Base PowerCharger ^{4X4} while in the aeromedical evacuation environment:

   A. Attach a "Caution" label on the ZOLL Base PowerCharger ^{4X4} that reads, **"Do not operate on 115 VAC/400 Hz."**

B. Do not place PowerCharger ^{4X4} directly on a blanket when securing to NATO litter. Doing so may obstruct vents on the bottom of the unit and prevent proper dissipation of heat during operation. AFMEDF recommends aluminum brackets be used for securing or place on flat/firm surface such as a small section of smooth plywood. Litter straps should not obstruct vents.

C. AFMEDF does not recommend that ZOLL Battery PD4410 or ZOLL Smart Battery PD4410 from the MonoPhasic and BiPhasic units be used with the ZOLL PD 4420 battery charger due to manufacturer's warnings about 4410 batteries overheating without special precautions being taken.

D. Manufacturer recommends battery replacement every eighteen months or sooner.

E. No transport case was evaluated. Care needs to be taken during transport to prevent damage to ZOLL Base PowerCharger ^{4X4}.

F. AFMEDF anticipates aeromedical evacuation crewmembers will secure ZOLL ^{4x4} with litter straps causing obstruction of "Caution" label on top surface of unit. Recommend "Caution" label and ZOLL logo positions be switched.

G. Recommend "Fault" light illumination be red instead of green for more noticeable display of fault indication.

Power Requirements:

110 VAC, 50-60 Hz input; 220-240 VAC, 50-60 Hz input

Procurement: Manufacturer

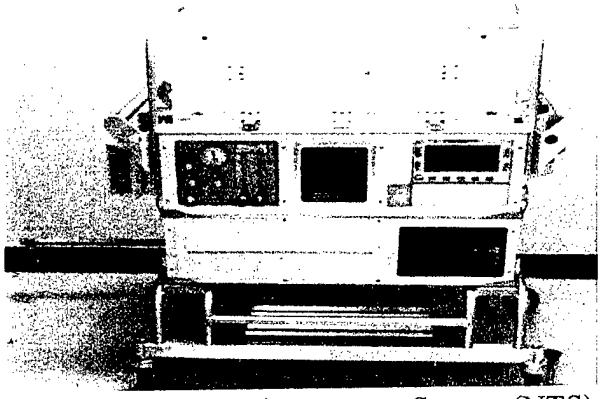
Reference: Technical Report number: AFRL-HE-BR-TR-2001-0072

INCUBATORS

- INTERNATIONAL BIOMEDICAL, INC., MODEL 20M, NEONATAL TRANSPORT SYSTEM
- INTERNATIONAL BIOMEDICAL, INC., MODEL 185 M AIRBORNE LIFE SUPPORT SYSTEM (ALSS)
- NEONATAL /PEDIATRIC ECMO TRANSPORT SYSTEM, MODEL WHMC-96

Product and Manufacturer

INTERNATIONAL BIOMEDICAL, INC., MODEL 20M, NEONATAL TRANSPORT SYSTEM



International Biomedical, Inc.
8508 Cross Park Drive
Austin, TX 78754
(800) 433-5615

Date Evaluated: April 1999

Description:

The International Biomedical, Inc. Model 20M, Neonatal Transport System (NTS) is an infant transport incubator. It provides an environment to support an infant's requirements while being transported. The incubator's standard infant chamber circulates warmed air and comes equipped with one main door, one head door, and two hand ports. The incubator's main door allows access for infant placement inside the infant chamber as well as further access for medical care. To prevent excessive heat loss; the main door has hand ports to allow infant care without opening the main door. The incubator has an accessory module containing a Protocol vital signs monitor, an International Bio-Med MVP-10 ventilator, a Mine Safety Appliance oxygen analyzer, an Impact continuous/intermittent suction device, and intravenous infusions using up to four Baxter syringe pumps. The incubator provides medical grade oxygen and air using internal "Q" size tanks and/or external gas sources. The unit operates using 115 VAC/60 and 400 Hz and internal rechargeable battery. The unit weighs approximately 123.76 lbs. Its dimensions are 37.5 inches W. X 43.0 inches H. X 21.88 inches D.

Summary:

AFMEDF engineers found the NTS CONDITIONAL for use during all phases of flight on all USAF aircraft (including small and large body, fixed and rotary wing). The NTS may be used in flight operating on internal battery or powered from 115 VAC/60 Hz and 400 Hz aircraft power. However, the Propaq encore 206EL vital signs monitor and Baxter AS50 syringe pumps can only operate from internal batteries or 115 VAC/60 Hz power. These devices can not remain plugged into the NTS convenience outlets while the NTS is operating from 115 VAC/400 Hz aircraft power. The NTS underwent extensive internal and external Electromagnetic Interference/Compatibility (EMI) modifications. See below for list of modifications. The NTS could not meet AFMEDF's established requirements for clinical operation following challenges to hot and cold operational testing (120° F for 2 hours and 32° F for 2 hours). However, the NTS did operate according to manufacturer's specifications for ambient environments between 59° F to 98.6° F. Aircrews need to be aware of these ambient operating temperature thresholds and operate the NTS according to manufacturer's guidelines.

The following comments and recommendations apply to this NTS while in the aeromedical evacuation environment:

A. In certain aircraft such as the C-130/C-141, special training considerations may apply. Consider limitations due to aircraft ambient noise degrading effectiveness of audio alarms. NTS should be positioned to allow continuous visual alarm monitoring by aeromedical crewmembers throughout all phases of flight.

B. On C-9A aeromedical aircraft, the audible cues could be clearly heard and understood within 7 feet of the NTS without the use of hearing protection.

C. Warning labels are required, positioned both inside and outside aluminum access panel door on back of NTS concerning use of 115 VAC/400 Hz power and need to keep panel door closed during flight. 1) "WARNING" USE ONLY 400 HZ COMPATIBLE DEVICES DURING 400 HZ OPERATION. UNPLUG ANY DEVICE THAT CAN NOT SAFELY RUN ON 400 HZ POWER, I.E., PROPAQ ENCORE 206EL VITAL SIGNS MONITOR AND BAXTER AS50 SYRINGE PUMPS. 2) "WARNING" ACCESS PANEL MUST BE KEPT CLOSED DURING IN-FLIGHT OPERATION.

D. Label the Propaq Encore 206EL's power cable plug-in to allow ease of identification.

E. In keeping with Mil-Std-1472E, all warning, caution and note labels must be written using capital letters. All labels must be positioned to be visible to direct observation and correctly positioned for reading.

F. No transport case/cover was evaluated. Care needs to be taken during transport to prevent NTS damage and protect it from the environment.

G. Securing the NTS to the aircraft floor, AFMEDF requires two standard cargo tie-down straps running across the width of the NTS, through the Air/Oxygen cart between the supports in-back of the wheels. AFMEDF does not recommend using the NTS handle due to limitations on ancillary equipment accessibility and the possibility of handle breakage during ratcheting of the cargo tie-down straps.

H. For securing the NTS in Air Force ambulances, AFMEDF recommends procuring the Retractable Bar Fastener System from International Biomedical, Inc. (P/N: 3170686)

I. During infant transport the NTS requires a minimum of four personnel to load and unload the unit into and from the ambulance, as well as enplaning and deplaning from the aircraft. NOTE: AFMEDF SUGGESTS USING THE LITTER RAMP FOR ENPLANING AND DEPLANING ON C-9A AIRCRAFT AND USE THE CARGO RAMP ON C-17, C-130 AND C-141 AIRCRAFT.

J. Frequent opening of the side door may result in NTS infant chamber over-heating without alarm activation.

K. The Pressed Steel "Q" size tanks must be mounted in the Air/Oxygen cart to prevent regulators and valves from protruding from underneath NTS.

L. To prevent wear and damage to the Pressed Steel "Q" size tanks from the effects of vibration, AFMEDF suggests padding metal areas that come in contact with the Pressed Steel "Q" size tanks, i.e. the retaining bar and the "V" channels the tanks rest on.

M. The mattress in the infant chamber is not vented to relieve excess pressure during a decompression of the aircraft cabin. Suggest the manufacturer place a ¼ inch diameter vent hole on mattress ventral surface one inch from mattress edge one at all four corners and one at mid-point. Also suggest using ¼ inch velcro strip at cover closure. Instead of currently used wider velcro strip.

N. Wheels, located on left side of Air/Oxygen cart as you face the NTS, should be moved 90° outward or round frame corners to prevent possible injury to aeromedical personnel from sharp edges of Air/Oxygen cart frame.

O. Suggest manufacturer provide an opening in the plastic panel above the Air/Oxygen cart or lengthen the AC power cable another 12 inches to allow the NTS's AC power cable better access to 115 VAC/60 Hz outlets onboard C-9A aircraft.

P. The pull drawer was an added feature to allow ease of access to the Impact 326M suction device. The drawer reinforcements and the Impact 326M suction securing technique modifications made by International Biomedical, Inc., in response to vibration test data need to be retained.

Q. Ensure the Impact 326M and Propaq 206EL's power supplies are mounted in such a way for ease of reading manufacturer and power specifications. i.e., (voltages and amperages).

R. Below is a list of EMI modifications that must be implemented prior to use in flight:

1. EMI filter input power lines.
2. EMI filter the power line to the NTS light at the point where wiring enters the electronics compartment.
3. Place ferrite beads near the circuit card/board to EMI filter signals from the Temperature Probe.
4. EMI shield temperature sensor wire bundle from connector on the control board to temperature sensor ports on Airflow Tray.
5. Ensure the Control panel/display is electrically bonded to the NTS housing.
6. Incorporate a metalized coating to the underside of the Airflow Tray.
7. Enclose electronics compartment with a metal shield to prevent radiated frequencies from entering and escaping the electronics compartment.
8. Place a conductive cover to the apertures on the back side of the NTS where the electrical receptacles are located.

S. To answer a question regarding noise attenuation in the infant chamber, AFMEDF

conducted a noise level assessment of the infant chamber during vibration testing. The purpose of the test was to examine whether additional noise inside the infant chamber was generated due to a change in manufacturing design of the plexi-glass hood. The evaluated hood is composed of two separate pieces versus the previous single piece design. The results demonstrated that the new plexi-glass hood does not generate additional environmental noise. Testing showed decreased environmental noise inside the infant chamber when compared to ambient conditions.

T. Baxter AS50 syringe pumps can not be stored above 130° F.

Power Requirements:

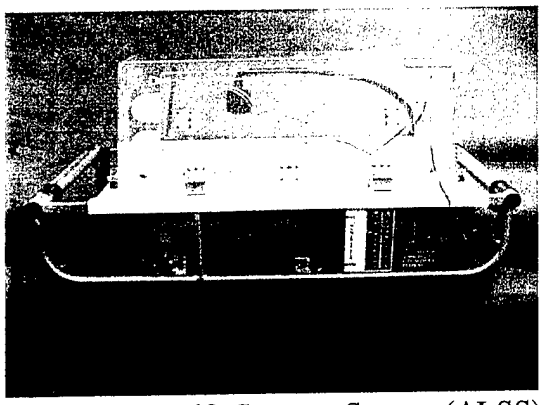
The NTS may be used in flight operating on internal battery or powered from 115 VAC/60 Hz and 400 Hz aircraft power. However, the Propaq encore 206EL vital signs monitor and Baxter AS50 syringe pumps can only operate from internal batteries or 115 VAC/60 Hz power. These devices can not remain plugged into the NTS convenience outlets while the NTS is operating from 115 VAC/400 Hz aircraft power.

Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-2000-0029

Product and Manufacturer

INTERNATIONAL BIOMEDICAL, INC., MODEL 185 M AIRBORNE LIFE SUPPORT SYSTEM (ALSS)



International Biomedical, Inc.
8508 Cross Park Dr.
Austin, TX 78754
Telephone: (512) 873-0033

Date Evaluated: January 2000

Description:

The International Biomedical, Inc., Model 185 M Airborne Life Support System (ALSS) is an infant transport incubator. It provides an environment to sustain an infant's life support requirements while being transported. The ALSS's standard infant chamber circulates heated air and comes equipped with one main door, one head door, and two hand ports. The ALSS's main door allows access for infant placement inside the infant chamber as well as further access for medical care. To prevent excessive heat loss, the main door has hand ports to allow infant care without opening the main door. The ALSS provides medical grade oxygen using "E" size tanks secured underneath the unit.

Summary:

AFMEDF engineers found the International Biomedical, Inc., Model 185 M Airborne Life Support System CONDITIONAL for use during all phases of flight on all USAF aircraft (including small and large body, fixed and rotary wing). The ALSS may be used in flight operating on internal battery or powered from 115 VAC/60 Hz and 400 Hz aircraft power. The ALSS underwent internal and external Electromagnetic Interference/Compatibility (EMI) modifications. The ALSS could not meet AFMEDF's established requirements for clinical operation following challenges to hot and cold operational testing (120° F for 2 hours and 32° F for 2 hours). However, the ALSS did operate according to manufacturer's specifications for ambient environments between 59° F to 98.6° F. Aircrews need to be aware of these ambient operating temperature thresholds and operate the ALSS according to manufacturer's guidelines. The following comments and recommendations apply to the ALSS while in the aeromedical evacuation environment:

A. In certain aircraft such as the C-130/C-141, special training considerations may apply. Consider limitations due to aircraft ambient noise degrading effectiveness of audio alarms. ALSS should be positioned to allow continuous visual alarm monitoring by aeromedical crewmembers throughout all phases of flight.

B. On C-9A aeromedical aircraft, the audible cues could be clearly heard and understood within 7 feet of the ALSS without the use of hearing protection.

C. In keeping with Mil-Std-1472E, all warning, caution and note labels must be written using capital letters. All labels must be positioned to be visible to direct observation and correctly positioned for reading.

D. No transport case/cover was evaluated. Care needs to be taken during transport to prevent ALSS damage and protect it from the environment.

E. Securing the ALSS to the NATO litter requires two standard NATO litter straps and the four securing straps provided by the manufacturer.

F. During infant transport, an occupied ALSS secured to a NATO litter, requires a minimum of four personnel to load and unload the unit into and from the ambulance, as well as enplaning and deplaning from the aircraft.

NOTE: AFMEDF SUGGESTS USING THE LITTER RAMP FOR ENPLANING AND DEPLANING ON C-9A AIRCRAFT AND USING THE CARGO RAMP ON C-17, C-130 AND C-141 AIRCRAFT.

G. Frequent opening of the side door may result in ALSS infant chamber over-heating without alarm activation.

H. The oxygen tanks must be mounted beneath the ALSS to prevent regulators and valves from protruding from the ALSS.

I. The mattress in the infant chamber is not vented to relieve excess pressure during a decompression of the aircraft cabin. Suggest the manufacturer place a ¼ inch diameter vent hole on mattress ventral surface one inch from mattress edges and in the middle. Also suggest using ¼ inch velcro strip at cover closure instead of currently used wider velcro strip.

J. Below is a list of EMI modifications that must be implemented prior to use in flight:

1. EMI filter input power lines.
2. EMI filter the power line to the ALSS light at the point where wiring enters the electronics compartment.
3. Place ferrite beads near the circuit card/board to EMI filter signals from the Temperature Probe.
4. EMI shield temperature sensor wire bundle from connector on the control board to temperature sensor ports on Airflow Tray.
5. Ensure the Control panel/display is electrically bonded to the ALSS housing.
6. Incorporate a metalized coating to the underside of the Airflow Tray.
7. Use only 40 inch-long skin temperature probe.
8. A copper-grounding strip needs to be attached to the securing plate for the control panel to provide contact with the Airflow Tray.

K. To answer a question regarding noise in the infant chamber, AFMEDF conducted a noise level assessment of the infant chamber during vibration testing. The purpose of

the test was to examine whether additional noise inside the infant chamber was generated due to a change in manufacturing design of the plexi-glass hood. The evaluated hood is identical to the ALSS hood and is composed of two separate pieces versus the previous single piece design. The results demonstrated that the new plexi-glass hood does not generate additional environmental noise. Testing showed decreased environmental noise inside the infant chamber when compared to ambient conditions.

Power Requirements:

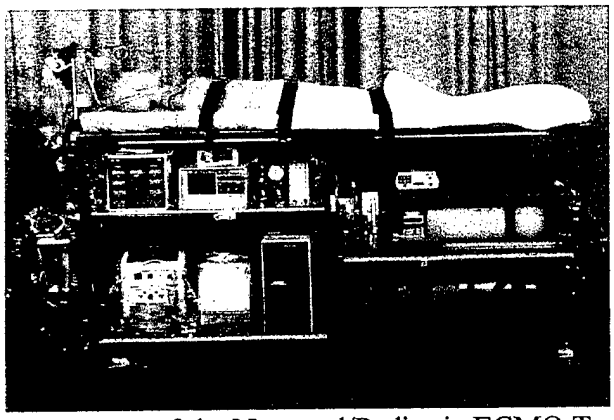
The unit operates on 115 VAC/60 & 400 Hz and internal rechargeable battery.

Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-2000-0066

Product and Manufacturer

NEONATAL /PEDIATRIC ECMO TRANSPORT SYSTEM, MODEL WHMC-96



Wilford Hall USAF Medical Center
Department of Pediatrics/PSP
2200 Bergquist Dr, Suite 1
Lackland AFB, TX 78236-5300
Telephone (210) 292-6679

Date Evaluated: April 1998

Description:

The following is a description of all the components of the Neonatal/Pediatric ECMO Transport System, Model WHMC-96:

CDI, 3M Health Care CDI 400 Extracorporeal Blood Gas Monitoring System

The CDI 400 provides continuous, on-line monitoring of extracorporeal pH, PCO_2, PO_2, temperature, calculated arterial base excess (BE) or bicarbonate (HCO_3), and venous oxygen saturation (S_vO_2). It is intended for continuous monitoring of blood gas and pH during cardiopulmonary bypass procedures. The CDI 400 utilizes a microprocessor based monitor and optical fluorescence technology. The fiberoptic cable assemblies (one venous and one arterial) connect the monitor to a disposable sensor and flow-through cell inserted into the extracorporeal circuit. Light pulses originating from a flash lamp located in the monitor pass through optical filters so light pulses of a specific frequency are transmitted down the fiberoptic bundles to the microsensors. The microsensors are composed of fluorescent chemicals which emit light in response to the stimulating pulses. The intensity of this emitted light depends upon the concentration of oxygen, carbon dioxide, and hydrogen ions passing through the gas and ion permeable membrane. The light emitted by the fluorescent microsensors is returned to the monitor through receiving optical fibers in the fiberoptic bundle. A filter is used to isolate the specific frequencies of interest from the returning light spectrum for measurement by a light detector. The output signal of the detector is converted by the microprocessor to a numerical readout in millimeters of mercury (mm Hg), kilopascals (kPa), or pH units which is displayed on the face of the monitor. The CDI 400 also displays calculated values for either the arterial base excess (mEq/L) or arterial bicarbonate concentration (mEq/L) and venous hemoglobin O_2 saturation (%). The CDI 400 operates from 115 VAC/60 Hz power and weighs 16.3 lbs. The dimensions are 9.5 inches H. X 9.75 inches W. X 9 inches D.

Modified Tripplite® Isobar Model IB-4 Noise Filter and Transient Voltage Surge Suppresser

The modified IB-4 provides noise filtering and transient voltage surge suppression and reduces conducted emissions in excess of MIL-STD-461D. See Appendix II for modification procedures.

Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit (2)

The SMS-3000 provides a flow of temperature controlled water to a heat exchanger. This heat

exchanger is connected in the blood flow path in series between the oxygenator and the patient during an ECMO procedure. It provides a means for warming and controlling blood temperature prior to and during perfusion. The SMS-3000 consists of a plastic reservoir for holding distilled water; a float switch to indicate low water level, a pump for circulating water through an external heat exchanger, a heating element to warm the water, a microprocessor-based electronic control to regulate water temperature, two independent back-up high limit devices to protect the patient and the unit, a water flow indicator to provide visual assurance of proper water flow, two connecting hoses for attachment of the heat exchanger, and a fan for removing heat generated within the unit enclosure. A phone jack marked "Blood Probe" allows connection of a 400 series-type thermistor probe for monitoring and/or controlling blood temperature. The control panel offers two modes of operation: "Water Temp" and "Blood Temp". In the "Water Temp" mode, the operator selects the desired water temperature setpoint and the SMS-3000 maintains the water at that temperature. In the "Blood Temp" mode, the operator selects the desired blood temperature as measured by the remote probe, and the SMS-3000 regulates the water temperature to maintain the blood temperature at the setpoint. The "Blood Temp" mode was not evaluated because the ECMO team did not require this mode. Audible and visual alarms indicate "Add Water", "Under Setpoint", "Over Setpoint", and "High Limit". Digital displays indicate water temperature, setpoint, and blood temperature (when a probe is connected) in degrees centigrade. The SMS-3000 operates from 115 VAC/60 Hz power and weighs 24 lbs (dry). The dimensions are 9.75 inches W. X 14 inches H. X 11 inches D.

Stöckert Shiley Multiflow Roller Pump Module, 10H Series, Model 10-10-00 (3)

The Model 10-10-00 roller pump is a 115 VAC/60 Hz precision peristaltic pump, which is the principle component of the Neonatal/Pediatric ECMO Transport System. The Model 10-10-00 roller pump as installed on the Neonatal/ Pediatric ECMO Transport Gurney includes a Venous Controller, often referred to as a "bladder box", and a Topaz Uniterruptible Power Supply which powers the roller pump if AC power is interrupted. The Model 10-10-00 roller pump is plugged into the bladder box. The bladder box is placed in the "Run" mode, and plugged into the modified Tripplite Isobar. The modified Tripplite Isobar is plugged into the Topaz. The Topaz is plugged into aircraft 115 VAC/60 Hz power. An example of this sequence is listed as follows:

Roller Pump → Bladder box → Modified Tripplite Isobar → Topaz UPS → 115 VAC/60 Hz power.

The Model 10-10-00 roller pump accommodates a wide range of flow rates using different tubing diameters together with different size tubing inserts available for the monitor. It is capable of displaying both revolutions per minute (RPM) and flow rates in LPM. Only LPM should be displayed during an ECMO transport. The Model 10-10-00 roller pump weighs 55 lbs and dimensions are 7.1 inches W. X 11.3 inches H. X 18.3 inches D.

Topaz Uniterruptible Power Supply (UPS), Model 84126-01

The Topaz UPS provides portable operating power, 115 VAC/60 Hz, to the multiflow roller pump and blood warming unit, which do not have internal battery power for ground transport to and from the aircraft. Once loaded on board the aircraft, the Topaz UPS is connected to the aircraft's 115 VAC/60 Hz power supply. The Topaz UPS weighs 90 lbs and dimensions are 7 inches W. X 15 inches H. X 18 inches D. The Topaz UPS was previously approved for use on the C-9A aircraft and is therefore only approved for use on large bodied aircraft. It produced radiated emissions, while operating on internal batteries, exceeding limits of the military standard for electromagnetic emissions and susceptibility. The Topaz UPS cannot be used on board any

military aircraft while operating on internal batteries. Emissions levels while operating on 115 VAC/60 Hz aircraft power were within acceptable limits.

Venous Controller/Blood Pump Regulator

The Venous Controller (referred to as a "bladder box") is a locally fabricated device that holds the venous reservoir (bladder). The bladder box is plugged into 115 VAC/60 Hz power. Power is directed through a microswitch to the roller pump. It is imperative the pump be plugged into the receptacle in the bladder box and not directly into a 115 VAC/60 Hz outlet, otherwise there will be no servo control of the pump output. When the bladder is distended the switch head is depressed and current flows to the pump. Conversely when the bladder empties the switch circuit is broken and power to the pump is interrupted (4). The bladder box weighs 3 lbs.

Neonatal/Pediatric ECMO Transport Gurney, Model WHMC-96

The gurney weighed 210 lbs empty, 742 lbs loaded (equipment only) with dimensions of 20 inches W. X 40 inches H. X 72 inches L. The gurney can accommodate a 20 inches X 40 inches bassinet for neonates and infants, or a 20 inches X 72 inches mattress pad for larger patients secured to the patient platform. Other specifications are listed in attachment 1. Throughout this report, the term gurney refers to the WHMC-96 Neonatal/Pediatric ECMO Transport Gurney. The components are secured underneath the patient platform on the left side of the gurney. The compressed gas cylinder mounting compartments accommodate 1 standard size Q cylinder containing oxygen, 1 standard size Q cylinder containing air, and 1 large size Q cylinder containing carbogen. The compressed gas cylinder mounting compartments are secured underneath the patient platform on the right side of the gurney. The left side of the gurney is designated as the head of the gurney, and the right side is designated as the foot.

Due to the size and weight, the Neonatal/Pediatric ECMO Transport System, Model WHMC-96 will only be approved for large bodied USAF aircraft. In addition, the Topaz UPS which provides battery power during ground transportation is only approved for use on large bodied aircraft.

Summary:

Testing and evaluation found the Neonatal/Pediatric ECMO Transport System, Model WHMC-96 CONDITIONAL for use on large bodied U.S. Air Force aeromedical evacuation aircraft. Due to the size and weight of this system, it is only approved for large bodied aircraft such as the C-130, C-141, C-9A, etc. The components of the ECMO Transport System are approved for use during all phases of flight unless otherwise specified below. Plywood planks (1 ft x 1 ft x 3/8 inch) were provided to the ECMO team for the purpose of shoring the aircraft floor. We recommend that plywood shoring be used during all ECMO transports on all aircraft. Please note the recommendations and operational restrictions listed below.

1. CDI, 3M Health Care CDI 400 (modified) Extracorporeal Blood Gas Monitoring System

The modified CDI 400, Serial No. 5631 operated within expected parameters when subjected to vibration, Electromagnetic Interference (EMI), environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. It is acceptable for use during all phases of flight on all Air Force aircraft while operating from 115 VAC/60 Hz or battery power.

2. CDI, 3M Health Care CDI 400 (unmodified) Extracorporeal Blood Gas Monitoring System
All unmodified CDI 400 Extracorporeal Blood Gas Monitoring Systems are conditionally acceptable for use, and may only be used in-flight. Unmodified CDI 400 Monitors are not certified for use below 10,000 feet AGL, as their emissions exceed the limits of MIL-STD-461D. This means that an unmodified CDI 400 must be turned off during takeoff and landing. The CDI 400 Monitor may be shut off without loss of the most recent calibration data (13). It may be used in-flight on all Air Force aircraft while operating from 115 VAC/60 Hz or battery power only.

3. Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit
Its operation was within expected parameters when subjected to vibration, electromagnetic interference (EMI), cold and humid environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. Since the SMS-3000 operated within expected parameters during the airborne performance phases of testing it is deemed conditionally acceptable for use. The following requirements apply:

A. Must be plugged into a modified Tripplite Isobar Model IB-4 noise filter and transient voltage surge suppresser to reduce EMI below limits

B. The set-point temperature must be adjusted if the ambient temperature at the enplaning or deplaning station exceeds 29.5°C (85°F).

4. Stöckert Shiley Multiflow Roller Pump Module, 10H Series, Model 10-10-00
Its operation was within expected parameters when subjected to vibration, cold and humid environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. The maximum flowrate authorized is 5.82 LPM since the pump exceeded EMI limits when the flowrate was set above 5.82 LPM. The pump is conditionally approved for use, however, the following requirements apply:

A. Plugged-in as follows:

1) Plugged-in in series into the Venous Controller/Blood Pump Regulator ("bladder box"), then the modified Tripplite Isobar, then the Topaz UPS, then into 115 VAC/60 Hz aircraft power

Example:

Roller Pump → Bladder box → Modified Tripplite Isobar → Topaz UPS → 115 VAC/60 Hz power

2) Must be plugged into a modified Tripplite® Isobar Model IB-4 noise filter and transient voltage surge suppresser to reduce EMI below limits

3) Must be plugged into a Topaz UPS to provide battery support during ground transport
Note: The Topaz UPS is only approved for large bodied aircraft

B. Flowrate set at 5.82 LPM or less.

5. Neonatal/Pediatric ECMO Transport Gurney, Model WHMC-96

A. The components of the ECMO Transport System are secured to the gurney. At the user discretion, medical equipment previously found acceptable for use for aeromedical evacuation may be used with the ECMO Transport System.

B. All the components of the ECMO Transport System are to be positioned, secured, set-up, and operated by ECMO team members at the hospital prior to arrival at the aircraft.

C. Loading: Use eight individuals (four on each side of the gurney) to unload gurney from the ambulance. Use seven individuals (three on each side and one at the bottom end) to roll up aircraft ramp.

D. Capped/uncapped Q cylinders secured in the mounting compartments are approved for in-flight use on all large body USAF aircraft .

E. Use boards or planks for shoring aircraft floor.

F. The securing of the gurney should be done by AECMs or loadmasters.

G. Secure the gurney as follows:

1) C-141 or Other Cargo Aircraft

a) The procedure requires four D-rings, two cargo tie-down straps, and plywood planks or boards used for shoring the aircraft floor.
b) According to load plan, roll the gurney to the identified litter tier.
c) At the discretion of the MCD/CMT and loadmaster the gurney may be placed between a centerline stanchion.
d) The restraining cables must be removed if the gurney is to be positioned between a centerline stanchion.
e) Position the gurney between two seat tracks.
f) Prior to securing, place 12 inch x 12 & 3/8 inch plywood planks next to each wheel.
g) Roll gurney onto plywood planks.
h) Engage the caster locking mechanism.
i) Position and secure D-Rings (1 each) to each seat track approximately 12 inches aft and 12 inches forward of gurney.
j) Secure each end of the gurney with one cargo tie-down strap.
k) At the head of the gurney, route one cargo tie-down strap from one D-ring through the gurney securing handles and secured to the other D-ring.
l) At the foot of the gurney, route one cargo tie-down strap from one D-ring through the gurney securing handles and secured to the other D-ring.
m) Plug the Topaz UPS into the electrical frequency converter.

2) C-9A Aircraft With The Support Stanchion and Combination Utility Stanchion in the Stowed Position.

a) The procedure requires 4 D-rings, two cargo tie-down straps, and plywood planks or boards used for shoring the aircraft floor.
b) At the discretion of the MCD/CMT the gurney may be placed in this configuration.
c) Determine at what litter tier the gurney will be positioned.
d) Stow the support stanchion and combination utility stanchion in the horizontal position.
e) Position the gurney between the inboard and outboard seat tracks.
f) Prior to securing, place 12 inch x 12 & 3/8 inch plywood planks next to each wheel.
g) Roll gurney onto plywood planks.
h) Engage the caster locking mechanism.
i) Position and secure D-Rings (1 each) to each seat track approximately 1 foot aft and 1 foot forward of gurney.
j) Secure each end of the gurney with one cargo tie-down strap.
k) At the head of the gurney, route one cargo tie-down strap from one D-ring through the gurney securing handles and secured to the other D-ring
l) At the foot of the gurney, route one cargo tie-down strap from one D-ring through the gurney securing handles and secured to the other D-ring.
m) Plug the Topaz UPS into 115 VAC/60 Hz aircraft power.

3) C-9A Aircraft With The Support Stanchion And Combination Utility Stanchion In The Litter Configuration

a) The procedure requires two D-rings, two cargo tie-down straps, and plywood planks or boards used for shoring the aircraft floor.
b) At the discretion of the MCD/CMT the gurney may be placed in this configuration.
c) According to load plan roll the gurney to the identified litter tier.
d) Position the gurney over the inboard seat track.
e) Prior to securing, place 12 inch x 12 inch & 3/8 inch plywood planks next to each wheel.
f) Roll gurney onto plywood planks.
g) Position and secure D-Rings (1each) to each seat track approximately 1 foot aft and 1 foot forward of gurney.
h) Secure each end of the gurney with 1 cargo tie-down strap.
i) Engage the caster locking mechanism.
j) At the head of the gurney, route one cargo tie-down strap from one D-ring through the gurney securing handles and secured to the same D-ring.
k) At the foot of the gurney, route one cargo tie-down strap from one D-ring through the gurney securing handles and secured to the other D-ring.
l) Plug the Topaz UPS into 115 VAC/60 Hz aircraft power.

6. Required support equipment supplied by the aeromedical evacuation squadron (AES):

A. One Timeter Aridyne medical air compressor, model 3500 or compressed air cylinders.

B. One electrical frequency converter is required on cargo aircraft

7. Required support equipment supplied by WHMC:

   A. ECMO support cart (1each), designed to secure two "Q" Cylinders and one "D" Cylinder. See Appendix III for approval letter.

   B. Unicell ECMO transport storage cabinet (2 each)

   C. Blue ECMO transport box (1 each)

   D. Transport suitcases (2 each)

   E. S-Scort portable suction (1 each) for ground transportation use

   F. Miscellaneous supply items deemed necessary by the ECMO team

Reference: Technical Report number: AFRL-HE-BR-TR-2000-0052

APPENDIX I
NEONATAL/PEDIATRIC ECMO
TRANSPORT SYSTEM, MODEL WHMC-96
SPECIFICATIONS

Dimensions

Neonatal/Pediatric ECMO Transport Gurney, Model WHMC-96

Length	72 inches
Width	20 inches
Height	40 inches

Weight

CDI 400	16.3 lbs
Gurney (empty)	210 lbs
Gurney (loaded)	742 lbs
Misc. ECMO equipment	8.2 lbs
Modified Tripplite® Isobar Model IB-4	1.5 lbs
Seabrook Model SMS-3000	28 lbs(wet)
Stöckert Shiley Multiflow Roller Pump	55 lbs
Topaz Uniterruptible Power Supply, Model 84126-01.	90 lbs
Venous Controller/Blood Pump Regulator	3 lbs
Q-Tank (reg. size, 36 lbs, 2 ea)	72 lbs
Q-Tank (large size, 58 lbs, 1 ea)	58 lbs

NOTE:

1. The square tubing used to construct gurney frame was steel 1 inch x 1 inch x 0.63, No. 4130, total tubing weight is 96 lbs.
2. If 1 inch x 1 inch x 0.63, No. 6063, square aluminum tubing was used the total gurney frame weight would be 72 lbs

Power Requirements

1. CDI 400
   a. 115 VAC/60 Hz using battery charger/AC adapter
   b. 12 volt, 6 amp-hour rechargeable battery
2. Seabrook Model SMS-3000
   a. 100 to 250 VAC/50 or 60 Hz, 320 watts, max.
   b. The Topaz UPS serves as the external battery
3. Stöckert Shiley Multiflow Roller Pump
   a. 100 to 250 VAC/50 or 60 Hz, 320 watts, max.
   b. The Topaz UPS serves as the external battery
4. Modified Tripplite® Isobar Model IB-4
5. Topaz Uniterruptible Power Supply, Model 84126-01
   a. 102-132 VAC/60 Hz
   b. Internal batteries, two 12V, 28 Amp-hour total, sealed gel cell, lead acid
   c. Output: 120 ± 3.5 VAC/60 ± 1 Hz, 1000 VA
6. Venous Controller/Blood Pump Regulator
   115 VAC/60 Hz, 3 amp fuse

APPENDIX II

MODIFICATION PROCEDURE FOR THE TRIPPLITE® ISOBAR, MODEL IB-4 NOISE FILTER AND TRANSIENT VOLTAGE SURGE SUPPRESSER

PURPOSE: To provides noise filter and transient voltage surge suppresser and reduce conducted emissions in excess of MIL-STD-461D for the following medical devices:

1. Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit
2. Stöckert Shiley Multiflow Roller Pump Module, 10H Series, Model 10-10-00, the Venous Controller/Blood Pump Regulator ("bladder box")

MODIFICATION PROCEDURES:

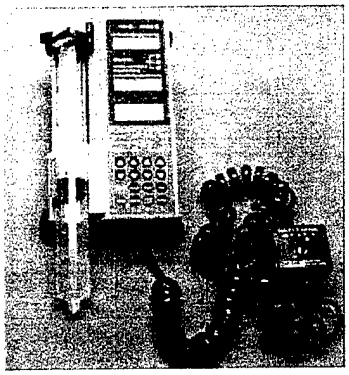
1. Remove the four screws from the end plate opposite the power cord.
2. Remove the end plate opposite the power cord.
3. Remove the bottom screw on the end plate holding the power cord.
4. Slide bottom half of unit to left and remove.
5. Turn unit upside down with power cord to the right.
6. Place the .033UFB 1600WVDC Type 715P Orange Drop Polypropylene Dipped Tubular Capacitor behind the blue capacitor on the left end on the PC board with the capacitor leads pointing toward the toroid in front of the blue capacitor.
7. Solder the left lead of the .033UFD capacitor to the left lead of the toroid.
8. Solder the left lead of the .033UFD capacitor to the right lead of the toroid.
9. Remove the left (white wire) connector from the power switch located next to the right end of the PC board.
10. Remove the center (black wire) connector from the power switch, and mark it "center" with masking tape.
11. Remove the right (black wire) connector from the power switch, and mark it "right with masking tape.
12. Remove the two screws on the top of the unit which are located between the power receptacles.
13. Lift the PC board upward and backwards.
14. Place the .047UFD 1600WVDC Type 715P Orange Drop Polypropylene Dipped Tubular Capacitor between the power switch and the circuit breaker with the capacitor leads pointing toward the power switch.
15. Replace the PC board in its original position.
16. Replace the two screws on the top of the unit which are located between the power receptacles.
17. Replace the connectors on the power switch in their original positions.
18. Solder the left lead of the .047UFD capacitor to the left connector on the power switch.
19. Solder the right lead of the .047UFD capacitor to the right connector on the power switch.
20. Slide the bottom half of the unit on.
21. Replace the end plate opposite the power cord.
22. Replace the four screws in the end plate opposite the power cord.
23. Replace the two bottom screws on the end plate with the power cord.

INFUSION

- BAXTER HEALTHCARE CORP., AUTO SYRINGE MODEL AS 20GH-2 INFUSION PUMP
- BAXTER HEALTHCARE CORP., AUTO SYRINGE MODEL AS50 INFUSION PUMP
- BIPRESS UNIVERSAL INFUSION DEVICE
- IVAC MEDSYSTEM III MULTI-CHANEL INFUSION PUMP AND IVAC AC POWER ADAPTER, MODEL 1555

Product and Manufacturer

BAXTER HEALTHCARE CORP., AUTO SYRINGE MODEL AS 20GH-2 INFUSION PUMP



Baxter Healthcare Corporation
P.O. Box 1748
Brentwood, TN 37024
Telephone (615) 373-1517

Date Evaluated: April 1995

Description:

The Baxter Healthcare Corp., Auto Syringe Model AS 20GH-2 Infusion Pump is a lightweight portable infusion pump capable of providing a prescribed dose directly in mcg/kg/minute, mcg/minute, or ml/hour, eliminating the need for conversion tables. Rechargeable nickel-cadmium batteries located inside the pump power the pump. These batteries should be charged using 105-125 VAC for at least 16 hours before the pump is placed in service. Battery life is rated at 5-24 hours, depending on product configuration, with a recharge time at 16 hours. In a hospital setting, the pump may be operated from 110 VAC or battery power.

Summary:

The Baxter Healthcare Corp., Auto Syringe Model AS 20GH-2 Infusion Pump is considered CONDITIONAL for in-flight use on all USAF aircraft provided the following requirements are met:

A. Operate on battery power only.

B. Do not charge the battery in-flight.

C. Charge the battery for 16 hours prior to flight.

D. Visually monitor unit for alarm activation.

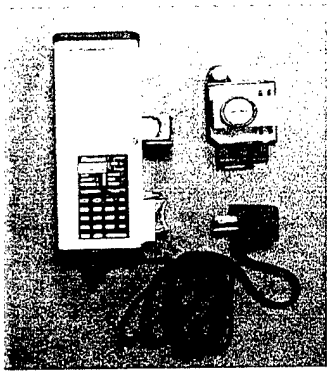
Power Requirements: Rechargeable nickel-cadmium batteries or 110 VAC

Procurement: Manufacturer

Reference: Technical Report number: AL/CF-TR-1996-0056

Product and Manufacturer

BAXTER HEALTHCARE CORP., AUTO SYRINGE MODEL AS50 INFUSION PUMP



Baxter Healthcare Corporation
P.O. Box 1748
Brentwood, TN 37024
Telephone (615) 373-3380

Date Evaluated: September 1998

Description:

The Baxter Healthcare Corp., Auto Syringe Model AS50 Infusion Pump is a portable, syringe type infusion pump. It provides accurate, continuous or intermittent infusion of intravenous solutions, drug solutions, whole-blood and packed red blood cells. The AS50 can be piggybacked into an ongoing infusion line to deliver a secondary solution. The AS50 can be programmed to set rates of infusion from 0.01 to 438 ml/hr. The AS50 accepts standard disposable syringes from 1 ml to 60 ml.

Summary:

The Baxter Healthcare Corp., Auto Syringe Model AS50 Infusion Pump is considered CONDITIONAL for use on all U.S. Air Force aeromedical evacuation aircraft while operating from 115 VAC/60 Hz and internal battery power. Its operation was within expected parameters when subjected to electromagnetic interference (EMI), environmental extremes, and simulated cabin altitudes. It did not produce a hazard to patient or crew during rapid decompression. The following recommendations apply:

A. Do not expose AS50 to ambient storage temperatures in excess of 130° F.

B. In certain aircraft such as the C-130/C-141 special training considerations may apply.

C. Consider limitations due to aircraft ambient noise affecting audio alarms. AS50 should be positioned to allow visual alarm monitoring throughout all phases of flight.

D. On military C-9A aeromedical aircraft, the audible cues could be clearly heard within 2 feet of the AS50 provided hearing protection was not used.

E. Battery charger is incompatible with USAF Electrical Cord Assembly System (ECAS). Recommend using the gray MS III pigtail adapter or similar power-cord extender when using ECAS. AS50 can be plugged directly into Avionics Instruments, Inc. frequency converter.

F. Securing the AS50 to NATO litters and aircraft stanchion poles is extremely difficult without impeding AS50 function. AS50 requires a securing system/device to

overcome this problem. The manufacturer supplied a litter-securing bracket during testing that proved very adaptable and rugged.

Power Requirements: 115 VAC/60 Hz and internal rechargeable battery

Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-2000-0031

Product and Manufacturer

BIPRESS UNIVERSAL INFUSION DEVICE

Bipress, Inc.
1680 Meridian Avenue, Suite 402
Miami Beach, FL 33139
Telephone (305) 534-4372

Date Evaluated: April 1996

Description:

The Bipress Universal Infusion Device is a portable IV infuser designed to deliver blood and other fluids contained in flexible bags of up to one-liter capacity. Its special design enables the Bipress to infuse fluids to the patient regardless of patient body position, lying or upright, by use of air pressure and maintaining drip chamber in a vertical position. The device eliminates the need for an IV pole or an extra person to hold the fluid bag. In addition, the Bipress is equipped with straps to allow use of the device by ambulatory patients. Bipress can be adjusted to deliver a fast infusion of blood or solution under pressure and continuous drip mode. Precise drip rate is difficult to achieve and Bipress recommends frequent monitoring during extended use.

Summary:

The evaluation of the Bipress Universal Infusion Device is complete. AFMEDF found the Bipress Universal Infusion Device to be ACCEPTABLE for use in USAF aeromedical evacuation aircraft.

A. Monitor function of the device during all phases of flight.

B. Provide instructions to inform users of the following: "As fluid levels in flexible containers decrease, the pressure valve will need to be readjusted to maintain infusion rate at preset levels."

C. Carry an extra bladder due to the possibility of bladder rupture. Use "ONLY" the green internal bladders made with the new polymer.

D. Use elastic securing straps with locking clips to hold IV bags in place in the event the unit experiences pressure loss.

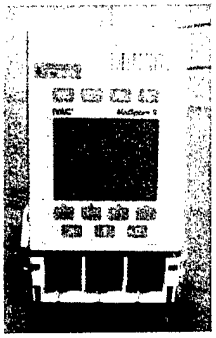
Power Requirements: None

Procurement: Manufacturer

Reference: Technical Report number: AL/CF-TR-1996-0070

Product and Manufacturer

IVAC MEDSYSTEM III MULTI-CHANNEL INFUSION PUMP AND IVAC AC POWER ADAPTER, MODEL 1555
IVAC-IMED
10221 Wateridge
San Diego, CA 92121-2733



Date Evaluated: June 1998

Description:

The MedSystem III is a multi-channel infusion pump which has three independent fluid delivery systems in the space of one. The MedSystem III provides an accurate delivery of a variety of fluids, and uses administration sets that provide free flow protection. The MedSystem III displays infusion status for rate, volume remaining and volume infused. The rate range is from 0.1 – 999 millimeters per hour on each channel. Infusions can be programmed to deliver at a specific rate or over a specified period of time. Secondary mode allows fluids and medication to be delivered sequentially at two different rates. Configuration parameters allow the user to essentially have six available device types to achieve specific clinical applications: General purpose, Neonatal, Controller Pressure, Operating Room, General Purpose II and Operating Room II. The different parameters include minimum rates, baseline and minimum volumes, baseline/maximum pressures, and air-in-line thresholds.

Summary:

AFMEDF found the IVAC MedSystem III and IVAC AC Power Adapter, Model 1555 to be ACCEPTABLE for use on all U.S. Air Force aeromedical evacuation aircraft while operating in the General Purpose mode of operation on 115 VAC/60 Hz or battery power with the recommendations listed below. Its operation was within expected parameters when subjected to vibration, Electromagnetic Interference (EMI), environmental extremes, simulated cabin altitudes and did not produce a hazard to patient or crew during rapid decompression testing.

A. Position infusion pump at the same level as the patient, or attach pump to the patient's litter.

B. Use on AC power when possible to conserve battery power.

Power Requirements:

The MedSystem III operates on 115 VAC/60 Hz and an internal rechargeable battery pack

Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-1998-0021

MISCELLANEOUS

- AIR METHODS CORPORATION, SPINAL CORD INJURY TRANSPORT SYSTEM (SCITS)

- BAYER CORPORATION GLUCOSE METER, MODEL ENCORE 5885A

- CEOTRONICS, INC., MODEL TC 917 WIRELESS HEADSET

- CEOTRONICS, INC., MODEL TC 917 (P/N: 0802160) WIRELESS HEADSET

- CDI™ 3M HEALTH CARE CDI™ 400 EXTRACORPOREAL BLOOD GAS MONITORING SYSTEM

- ELWYN E. ROBERTS ISOLATORS, LTD., TRANSIT ISOLATOR

- I-STAT BLOOD GAS ANALYZER

- LIFEPORT, INC. LIFEPORT PATIENT LOADING UTILITY SYSTEM

- NORTHROP GRUMMAN CORPORATION MODEL 9602 LIFE SUPPORT FOR TRAUMA AND TRANSPORT (LSTAT) UNIT PART NUMBER ATBX01006A002

- SEABROOK MEDICAL SYSTEMS, INC., ECMO-TEMP BLOOD WARMING UNIT, MODEL SMS-3000

- SOS, Ltd., HYPERLITE, EMERGENCY EVACUATION HYPERBARIC STRETCHER, MODEL 24/88/SAT/70

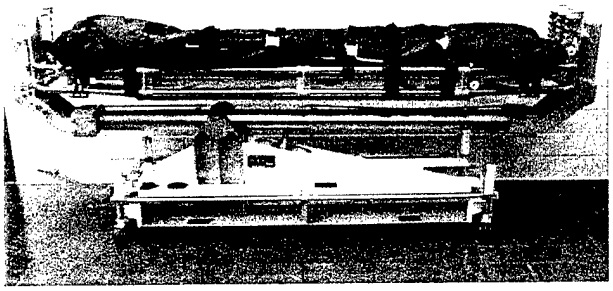
- SPECTRUM AEROMED, SPECTRUM 500-LP (MILITARY VERSION) MODEL 2500-US

- STÖCKERT SHILEY MULTIFLOW ROLLER PUMP MODULE, 10H SERIES, MODEL 10-10-00

Product and Manufacturer

AIR METHODS CORPORATION, SPINAL CORD INJURY TRANSPORT SYSTEM

Air Methods Corporation
7301 S. Peoria
Englewood, Colorado 80112



Date Evaluated: February 2000

Description:

The Spinal Cord Injury Transport System (SCITS) is a patient transport system designed to provide an increased level of patient care during aeromedical evacuation operations. The system mission is the evacuation of severely injured personnel, including spinal cord injury and burn victims from forward area care providers. The system can interface with a variety of aeromedical evacuation platforms as well as ground transport vehicles providing enhanced flexibility for transport. The pneumatic ambulatory traction device will provide pneumatic traction force to a patient's body in a manner that can be controlled and varied as needed. The SCITS can be used with accessories such as an IV pole and standard patient tray. This product is a combination of traction units and patient bed that are typically found to be separate units.

Summary:

1. The test and evaluation of the Air Methods Corporation, Spinal Cord Injury Transport System has been completed. AFMEDF found the SCITS "CONDITIONAL" for use during all phases of flight on all USAF aircraft (including fixed and rotary wing).

2. The following comments and recommendations apply to the Spinal Cord Injury Transport System:

A. Potential for increased morbidity during application of cervical traction while on SCITS during an aircraft in-flight rapid decompression.

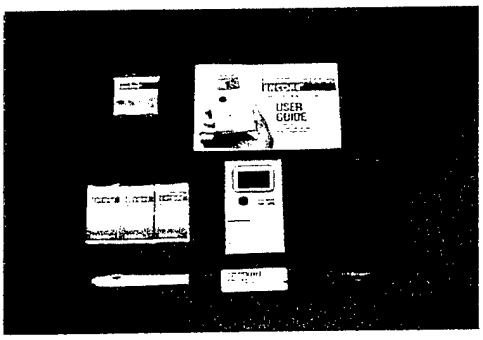
B. Operational Test & Evaluation of the SCITS on USAF aerovac and transport aircraft is deferred to HQ AMC. AFMEDF recommends pursuit of an air transportability certification letter issuance by ASC/ENFC.

Power Requirements: None

Procurement: HQ AMC/SGXPA

Product and Manufacturer

BAYER CORPORATION GLUCOSE METER, MODEL ENCORE 5885A



Bayer Corporation
Elkhart, IN 46515
(800) 348-8100

Date Evaluated: January 1999

Description:

The Bayer Corporation Glucose Meter, Model Encore 5885A is a hand-held, lightweight, compact, blood glucose monitoring system. It provides an easy way to test blood for glucose in the home or for professional use. It operates in a metered range between 10-600 mg/dl. It has the ability to store up to 10 recent blood glucose test results and provide an average of all stored tests. Encore 5885A operates off of two internal non-replaceable lithium batteries which will complete approximately 15,000 tests. After the batteries expire the Encore 5885A then becomes disposable. The Encore 5885A weighs approximately 0.38 lbs. with internal batteries and case.

Summary:

AFMEDF found the Bayer Corporation Glucose Meter, Model Encore 5885A to be CONDITIONAL for use on all U.S. Air Force aeromedical evacuation aircraft while operating from internal battery power.

Power Requirements:

Encore 5885A operates off of two internal, non-replaceable lithium batteries.

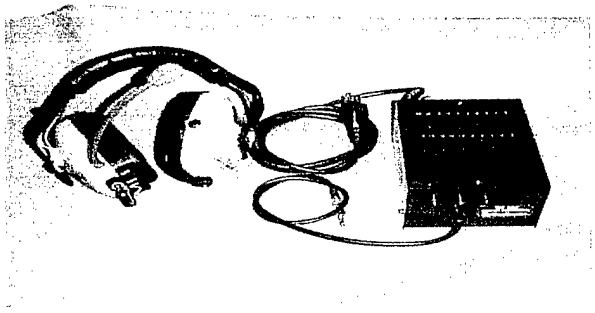
Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-2000-0032

Product and Manufacturer

CEOTRONICS, INC., MODEL TC 917 WIRELESS HEADSET

Ceotronics, Inc.
2340 Trinity Mills Rd. #112
Carrollton, TX 75006
Telephone: (972) 416-9500



Date Evaluated: February 1997

Description:

The Ceotronics, Inc. Model TC 917 Wireless Headset is a portable, battery operated, wireless headset. It allows hands-free voice communication with voice activation or push-to-talk capability. The headset came equipped with 10 channels ranging in frequency from 451.5 MHz to 453.75 MHz. Each step up or down the frequency range denotes a change in frequency of 0.25 MHz. Changing a channel involves removing the right ear cup and placing a small slotted screwdriver into the channel select arrow and rotating the arrow to the desired channel. Performs automatic self-tests and displays the results of these tests on a status indicator. The unit operates on an internal, rechargeable Ni-Cad battery and can be recharged using the single unit 115 VAC/60 Hz battery charger (P/N: 40 06 530). The headset weighs approximately 1.38 lbs. The single unit 115 VAC/60 Hz battery charger (P/N: 40 06 530) weighs 2.96 lbs. The charger is 4.28 inches W. X 3 inches H. X 6 inches D.

Summary:

AFMEDF found the Ceotronics, Inc., Model TC 917, wireless headset to be CONDITIONAL for use on all U.S. Air Force aeromedical evacuation aircraft while operating on the internal rechargeable Ni-Cad battery. Its operation was within expected parameters when subjected to electromagnetic interference (EMI), environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. The following recommendations apply:

A. Device can **only** be used onboard C-130H aircraft that has been retrofitted with a "glass cockpit" and onboard C-141 B aircraft that has **not** been retrofitted with a "glass cockpit" while operating from the internal Ni-Cad battery only. **Battery charger is not certified for flight!**

B. Voice quality degrades when using additional hearing protection (Ear plugs).

C. OPSEC/COMSEC concerns exist since no encryption voice technology is incorporated into the headset. Conversations conducted wearing the headset should be restricted from discussing classified or sensitive information.

D. Microphone placement must be within one finger width from lips for maximum voice clarity.

E. When using Voice Activation mode there is a time delay from when one person speaks to when the other person is clear to speak posing a training issue for crewmembers trying to teach patients how to use the headsets in flight.

F. Headset is not equipped with an external channel selection switch. Personnel must remove the headset in order to change channels/frequencies.

Power Requirements:

The unit operates on an internal, rechargeable Ni-Cad battery and can be recharged using the single unit 115 VAC/60 Hz battery charger (P/N 40 06 530).

Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-2000-0014

Product and Manufacturer

CEOTRONICS, INC., MODEL TC 917 (P/N: 0802160) WIRELESS HEADSET

Ceotronics, Inc.
2340 Trinity Mills Rd. #112
Carrollton, TX 75006
Telephone: (972) 416-9500

Date Evaluated: April 2000

Description:

The Ceotronics, Inc. Model TC 917 (P/N: 0802160) Wireless Headset is a portable, battery operated, wireless headset. It allows hands-free voice communication with voice activation or push-to-talk capability.

Summary:

1. The test and evaluation of the Ceotronics, Inc., Model TC-917 (P/N: 0802160) Wireless Headset has been completed. Air Force Medical Equipment Development Function (AFMEDF) found this unit CONDITIONAL for use during all phases of flight on Air Force C-130 and C-141 aircraft while operating on battery power in the aeromedical evacuation environment with the following comments and recommendation(s):

    A. Headsets were evaluated at distances of up to 750 feet apart with no degradation in performance.

    B. The Ceotronics Model SA-35-3153 Charger is acceptable for use during all phases of flight on all Fixed and Rotary wing Air Force aircraft.

- Note: As with any carry-on equipment, the pilot or crew should be notified of the headset use in flight and may prohibit operations of the wireless headset if interference is suspected.

2. Any headset as an active, intentional transmitter of radio frequency energy allows for potential interference both with aircraft systems and medical equipment devices on board. Aeromedical evacuation crew members and aircrew must remain vigilant and attentive to evidence of interference emanating from use of wireless headsets. Any suspected occurrences should be dealt with by immediate termination of headset use and reporting the incident including all particulars to HQ AMC/SGXPA for relay to this laboratory.

Power Requirements:

The unit operates on an internal, rechargeable Ni-Cad battery and can be recharged using the single unit 115 VAC/60 Hz battery charger.

Procurement: Manufacturer

Reference: AFRL Project # AMCXSUPT

Product and Manufacturer

CDI™ 3M HEALTH CARE CDI™ 400 EXTRACORPOREAL BLOOD GAS MONITORING SYSTEM

CDI 3M Health Care
1311 Valencia Ave.
Tustin, CA 92680
Telephone: (714) 258-8001

Date Evaluated: June 1998

Description:

The CDI™ 400 Extracorporeal Blood Gas Monitoring System provides continuous, on-line monitoring of extracorporeal pH, PCO_2, PO_2, temperature, calculated arterial base excess (BE) or bicarbonate (HCO_3), and venous oxygen saturation (S_vO_2). The CDI™ 400 is intended for use during cardiopulmonary bypass procedures when continuous blood gas and pH monitoring is desired. The CDI™ 400 utilizes a microprocessor-based monitor and optical fluorescence technology. The fiberoptic cable assemblies (one venous and one arterial) connect the monitor to a disposable sensor and flow-through cell inserted into the extracorporeal circuit. Light pulses originating from a flash lamp located in the monitor pass through optical filters so light pulses of a specific frequency are transmitted down the fiberoptic bundles to the microsensors. The microsensors are composed of fluorescent chemicals, which emit light in response to the stimulating pulses. The intensity of this emitted light depends upon the concentration of oxygen, carbon dioxide, and hydrogen ions passing through the gas-and ion- permeable membrane. The light emitted by the fluorescent microsensors is returned to the monitor through receiving optical fibers in the fiberoptic bundle. A filter is used to isolate the specific frequencies of interest from the returning light spectrum for measurement by a light detector. The output signal of the detector is converted by the microprocessor to a numerical readout in millimeters of mercury (mm Hg), kilopascals (kPa), or pH units which is displayed on the face of the monitor. The CDI™ 400 also displays calculated values for either the arterial base excess (mEq/L) or arterial bicarbonate concentration (mEq/L) and venous hemoglobin O_2 saturation (%). The CDI™ 400 operates from 115 VAC/60 Hz power and weighs 16.3 lbs. The dimensions are 9.5 inches H. X 9.75 inches W. X 9 inches D.

Summary:

AFMEDF found the modified CDI™ 400 Extracorporeal Blood Gas Monitoring System, Serial No. 5631 to be ACCEPTABLE for all phases of flight on all Air Force aircraft while operating from 115 VAC/60 Hz and battery power.

All unmodified CDI™ 400 Extracorporeal Blood Gas Monitoring Systems are conditionally acceptable for use. Unmodified CDI™ 400 Monitors are not certified for use below 10,000 feet, as their emissions exceed the limits of MIL-STD-461D. This means that an unmodified CDI™ 400 must be turned off during takeoff and landing. The CDI™ 400 Monitor

may be shut off without loss of the most recent calibration data. It may only be used in-flight on all Air Force aircraft while operating from 115 VAC/60 Hz and battery power.

The CDI™ 400 operation was within expected parameters when subjected to vibration, Electromagnetic Interference (EMI), environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. The following requirements apply:

A. Set up and operated by ECMO team members

B. Positioned and secured to the neonatal/pediatric ECMO transport cart

Power Requirements:

The CDI™ 400 operates from 115 VAC/60 Hz power

Procurement: Manufacturer

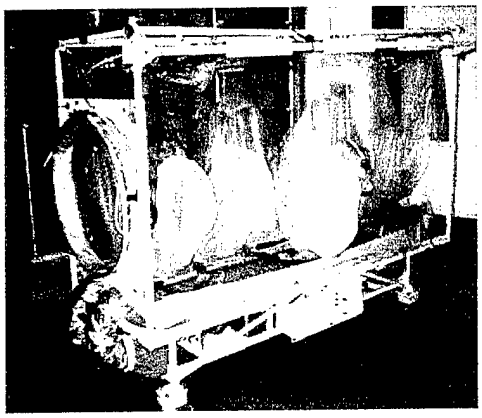
Reference: Technical Report number AFRL-HE-BR-TR-1998-0020

Product and Manufacturer

ELWYN E. ROBERTS ISOLATORS, LTD.,
TRANSIT ISOLATOR

Shropshire, England

Date Evaluated: May 2000



Description:

The Elwyn E. Roberts Transit Isolator is a self-contained transit isolator designed for the isolation of patients requiring transportation in aircraft where the need to maintain a strict microbiological security is required. Transit Isolator consists of a welded lower frame and attached baseboard which supports the air supply unit, filters, battery boxes, control panels and power switch box. The upper detachable frame is of lightweight tube construction and is assembled onto the lower framework by means of hand-tightened nuts and removable shear pins. The Isolator may be lifted using multi-purpose carrying handles or rolled on the casters attached to each of the 4 support legs that are part of the lower frame assembly. The U.S. Army Medical Research Institute of Infectious Diseases maintains an aeromedical isolation team who will be the major users of this device for air transport of a contaminated patient.

Summary:

1. The test and evaluation of the Aircraft Transport Isolator manufactured by Elwyn E. Roberts Isolators, Ltd., of Shropshire, England has been completed per request of Captain Herrold/ U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). AFMEDF reviewed all test data conducted by the U.S. Navy for USAMRIID as reflected in U.S. Navy published TR-9-01-00, Rev. A, pg. 10. AFMEDF found the Transport Isolator to be CONDITIONAL for use during all phases of flight on all USAF fixed wing aircraft (75 feet or longer) with the exception of USAF tanker aircraft. WRACC/TIECD engineers at Robins AFB, GA have not evaluated the Aircraft Transport Isolator for explosive atmosphere testing for compliance with MIL-STD 810F. HQ AMC/SGXP will be able to assist in coordinating future evaluation of this device for use onboard USAF tanker aircraft.

2. The following comments and recommendations apply to the Aircraft Transport Isolator:

   A. ASC/ENAE Wright-Patterson AFB evaluated Electromagnetic Interference test results and concluded that the Aircraft Transport Isolator is acceptable for Air Force large body aircraft (75 feet or longer). Approval includes operation on aircraft 28 VDC and internal batteries and with 115 VAC fluorescent lighting on.

   B. Review of test results conducted at the Aviation Survival Training Center, Patuxent River Maryland revealed 115 VAC fluorescent lighting of Aircraft Transport Isolator was not subjected to altitude and rapid decompression testing. Therefore, AFMEDF will not approve use of Isolator fluorescent lights for use in-flight until successful performance evaluation of above mentioned test results.

C. USAMRIID maintainers of Aircraft Transport Isolator should establish a routine maintenance inspection schedule for the Isolator. During the course of vibrational testing (refer to U.S. Navy published TR-9-01-00, Rev. A, pg. 10), several hardware components (screws, bolts, mounting brackets) came loose during vibration testing. In addition, vibration testing resulted in four capacitors separating from the electronic circuit board causing the Isolator to switch over to battery mode. The use of Lock-Tite, nylon nuts, or lock washers should be investigated as potential solutions to loosening hardware. Either the Isolator manufacturer or USAMRIID BMET maintainers should apply RTV or other suitable electronic component adherent to motherboard capacitor-junctions to reduce the possibility of capacitors or other electronic components from breaking off during aeromedical evacuation missions. AFMEDF recommends Isolator be thoroughly inspected for loose hardware and damage pre-mission and post-mission.

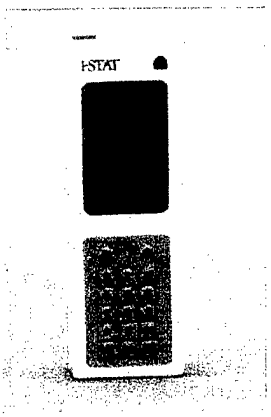
3. U.S. Navy technical report (TR-09-01-01) Environmental Test Report Flight Transport Isolator has been forwarded to HQ AMC/SGXP for reference.

Power Requirements: 28 VDC and internal batteries

Procurement: Manufacturer

Product and Manufacturer

i-STAT BLOOD GAS ANALYZER



i-STAT Corporation
303 College Road East
Princeton, NJ 08540
Telephone: (800) 827-7828

Date Evaluated: May 1998

Description:

The i-STAT, Inc., Blood Gas Analyzer is a portable hand-held unit designed to analyze and provide data on human blood, e.g., chemistries and blood gases. The unit uses cartridges and a very small amount of blood to analyze various parameters in the blood depending upon the cartridge being used.

Summary:

AFMEDF found the i-STAT Blood Gas Analyzer to be CONDITIONAL for use on all U.S. Air Force aeromedical evacuation aircraft during all phases of flight. The requirement that the operating temperature be within a very narrow range will present some problems but many hospitals have found ways to overcome this limitation, such as storing the unit in an Igloo® ice chest or placing the i-STAT inside of the flight suits worn by medical personnel. The operating range limitation is a restriction found on all blood gas analyzers evaluated by this organization. The failure of the filled cartridge to survive rapid decompression is not considered serious. The i-STAT and empty cartridges will survive rapid compression.

Power Requirement:

The unit operates on two 9 Volt-lithium batteries.

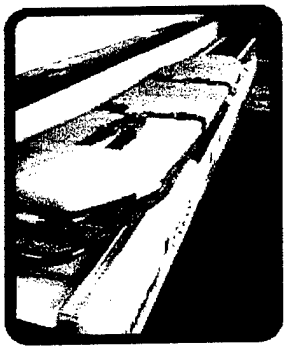
Procurement: Manufacturer

Reference: Technical Report number: AL/CF-BR-TR-1998-0013

Product and Manufacturer

LIFEPORT, INC. LIFEPORT PATIENT LOADING UTILITY SYSTEM

LifePort, Inc
12808 N.E. 95th Street
Vancouver, WA 98682
Telephone: (800) 854-8524



Date Evaluated: June 1997

Description:

The LifePort, Inc., LifePort Patient Loading Utility System (PLUS) is a six-foot patient care platform composed of the following features: a 124 cubic foot oxygen system with DISS of Ohio outlet which provides 3.8 hours of oxygen at 15 LPM; two 518 watt inverters with one wired as a back-up, and only one is operational at a time; a 28 VDC vacuum system rated at 22 inches Hg with DISS or Ohio outlets; two 28 VDC compressed air systems, each achieving 100 psi and regulated to 50 psi to a filling port and quantity gauge; an AeroSled Transport System (TS) with a pneumatically controlled backrest that adjusts from 0-60 degrees and also includes a patient safety restraint system; high density foam pad and cover; a loading system with a load ramp that attaches to the LifePort or a ramp bay and folds for storage; externally attached telescoping IV pole; suction canister; oxygen and air flow meters; and an AeroSled Arch that connects over the AeroSled TS used to mount life support equipment.

Summary:

AFMEDF found the LifePort, Inc., LifePort Patient Loading Utility System to be ACCEPTABLE for use on USAF aeromedical evacuation aircraft. The LifePort, PLUS was modified to pass environmental testing. The modification consisted of adding a second water trap and heat moisture exchanger to the air system in order to overcome water build up. The modified unit is designated as the LifePort, PLUS. This version is approved for all phases of flight on USAF aircraft. This unit was tested on the C-21A Learjet. Analysis of flight data indicated this unit was easy to enplane and deplane and was compatible with aircraft electrical systems. It was also noted that the power cord length might not be sufficient when securing the unit to the floor of the aircraft and may need to be lengthened to allow securing unit to the aircraft floor.

Power Requirements: The device operates using 28 VDC aircraft power.

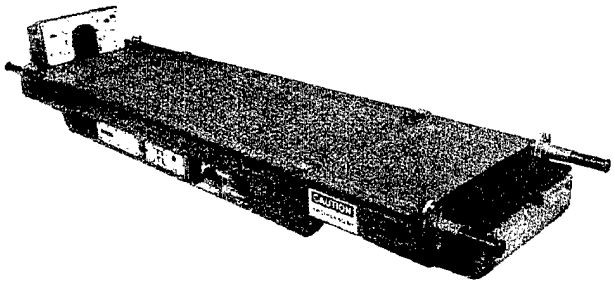
Procurement: Manufacturer

Reference: Technical Report number: AL-CF-BR-TR-1998-0011

Product and Manufacturer

NORTHROP GRUMMAN CORPORATION MODEL 9602 LIFE SUPPORT FOR TRAUMA AND TRANSPORT (LSTAT) UNIT PART NUMBER ATBX01006A002

Northrop Grumman Corporation
Advanced Systems & Technology
Telephone: (562) 948-9627



Date Evaluated: March 1997

Description:

Physical Description: The LSTAT is a portable individual intensive care unit (ICU) incorporated into a structure which serves as a resuscitation, stabilization, and evacuation platform for trauma casualty treatment. The casualty travels on the LSTAT. The LSTAT is designed to interface with multiple evacuation vehicles. The LSTAT platform accommodates standard NATO litters approximately 90 inches in length. The unit includes a head fairing with controls for medical device sub-components. The head fairing is approximately 13 inches high. The LSTAT is approximately 85.5 inches in length and 22 inches in width.

System Description: The LSTAT is a portable ICU platform designed to provide lifesaving and stabilizing therapies throughout the theater of operation. The LSTAT is designed to operate both in an austere forward environment and in static rear areas. It can operate in a temporary stand-alone configuration for short periods using internal resources or while utilizing existing external power, oxygen, and medical air resources for indefinite periods. A brief description of LSTAT sub-components follows:

Physiological Monitor: The LSTAT has the capability to continually monitor patient status and functions using a Protocol Systems Inc., Propaq Model 106 LCD physiological monitor. Monitoring functions include, Invasive Blood Pressure (2 channels), Non-Invasive Blood Pressure, ECG, arteriolar hemoglobin Oxygen Saturation (SpO_2), End-Tidal Carbon Dioxide ($ETCO_2$), Airway flow volume, and temperature (esophageal or skin). Each of the measured parameters has a known operating range and associated alarm condition based on set parameters. The monitored information is delivered to the DDLS and secondary display.

Suction Unit: The LSTAT incorporates an IMPACT Model 326 Continuous/ Intermittent Suction Unit (CISU) to remove secretions from the upper airway during oropharyngeal, nasopharyngeal and tracheal suctioning procedures. It is capable of being programmed to deliver intermittent suction intervals.

Ventilator: The IMPACT Corporation, Model 754 "Eagle" Transport Ventilator supplies the patient with medical grade air and medical grade oxygen via LSTATs on-board support systems or through external gas ports. It is capable of operating in either the Synchronized Intermittent Mandatory Ventilation (SIMV), Assist Control Ventilation (ACV) or

Continuous Positive Airway Pressure (CPAP) modes. A manual breath function allows the manual delivery of ventilation at any time. The ventilator is composed of an electronically controlled ventilator, compressor, air & oxygen blender. It is controlled by an internal microprocessor, which continuously monitors and displays airway pressure, control settings, alarm parameters, gas source(s), gas flows, gas blends, and power signals. ACV, SIMV, and CPAP modes are operable with or without Positive End Expiratory Pressure (PEEP). External (50±5 psi) medical air and oxygen gas line receptacles are also provided on either side of the LSTAT.

Defibrillator: The LSTAT uses a SurVivaLink Corporation, Automated External Defibrillator (AED). The SurVivaLink AED is a semi-automatic defibrillator that uses a shock advisory system. This software algorithm analyzes the patient's electrocardiograph (ECG) rhythm and indicates whether or not it detects a shockable rhythm. The AED requires operator interaction in order to defibrillate the patient. If the operator authorizes the discharge, then the discharge is applied through the patient monitoring/defibrillation electrodes. If the operator fails to authorize the shock application to the patient within 30 seconds, the charge is then dumped internally.

IV and Drug Administration: The LSTAT uses the IVAC MedSystem III Infusion Pump for IV fluid and drug administration. The MedSystem III Multi-Channel Infusion Pump can deliver 0.1-999 cc/hour on each of its three fluid administration channels. The pump possesses its own 6-hour Nickel-Cadmium operating battery, which allows it to function in the absence of power from the LSTAT. The unit also displays IV fluid types, rates, and related information to establish trends or other quantitations of input/output balance information into the Display and Data Logging Sub-system.

Clinical Analyzer: The LSTAT uses the i-STAT System to provide blood sample analysis. The i-STAT is portable, handheld and has the capability to perform various blood analysis tests using special cartridges. The i-STAT uses disposable cartridges, which once loaded with a blood sample are inserted into the instrument for analysis. The i-STAT can perform blood tests to measure sodium, potassium, chloride, glucose, urea nitrogen, hematocrit, ionized calcium, arterial blood gases, pH, PCO_2, PO_2, and bicarbonate. The i-STAT can also provide test results for carbon dioxide, base excess, anion gap, hemoglobin, and O_2 saturation by use of additional cartridges. The i-STAT operates on two 9 V lithium batteries. It can store up to 50 patient records and can transmit individual or groups of records via an infrared link to either a strip chart recorder or a central data station.

Oxygen System: A 480 gaseous Liter Bottle Exchange System is located at the foot of the LSTAT. It consists of a 3,000 psi reservoir and associated internally mounted supply lines delivering medical grade oxygen to the ventilator (50±5 psi) or by mask directly to a spontaneously breathing patient. The system provides oxygen for blended ventilation gas to the ventilator/patient. Sufficient oxygen is available for one hour of stand-alone operation running at 8 LPM. An external pressure gauge is provided to indicate the status of the internal oxygen reservoir and is also provided in an electronic read-out for data logging and status reporting. Capability to interface with external gas (oxygen and air) sources (50±5 psi) is also available. An accessory external oxygen hose with fittings is provided for this purpose. Oxygen is replenished via changeable/disposable bottles.

Display and Data Logging Subsystem (DDLS): The DDLS performs data logging functions to record patient physiological data and display operational status of LSTAT sub-systems. The DDLS also provides the LSTAT with a secondary means of displaying medical data using a Fujitsu, Model Stylistic 1000, pen based tablet computer. The DDLS does not control any of the life support (medical) equipment functions on the LSTAT. Control of the DDLS is through an operator interface or an off board computer (not part of the LSTAT). The DDLS has six operational modes: "Power-up," "Test," "Initialization," "Run," "Shutdown," "Maintenance," and "Off."

Electrical Power Subsystem (EPS): the EPS is self-contained and interfaces with auxiliary power through five separate power adapters. Internally mounted nickel-cadmium batteries are used to power the LSTAT and can be recharged in place or exchanged and externally recharged. The EPS has the capability to be recharged. Once fully charged, the EPS can operate on internal battery power for at least 30 minutes. The power system can operate from the following sources:

105-120 VAC/60Hz
108-118/200 VAC 3 Phase 400Hz
210-220 VAC/50Hz
25-30 VDC

The EPS provides a smooth uninterrupted transition between self-powered and auxiliary modes. Controls are provided for managing any power sources and supports the automatic recharging of self-contained power stores during periods of auxiliary power connection. According to manufacturer's specification, a completely discharged system can be completely recharged within 24 hours.

Summary:

AFMEDF found the Northrop Grumman Corporation Model 9602 Life Support for Trauma and Transport (LSTAT) unit part number ATBX01006A002, serial number 0002 to be CONDITIONAL for limited use on all U.S. Air Force aeromedical evacuation aircraft. In accordance with AFI 11-202V3, the LSTAT requires certification by AFMC/ASC/ENAE for electromagnetic interference/compatibility testing. The LSTAT should not be operated on any electrical power sources until such certification is achieved. Form and fit testing may proceed onboard USAF aircraft in coordination with HQ AMC/SGXR. The operation of some sub-components could not be demonstrated within expected parameters when subjected to environmental extremes and simulated cabin altitudes. The LSTAT did not produce a hazard to patient or crew during rapid decompression. The ultimate operational use of the LSTAT for actual patient care will be based upon its demonstrated performance characteristics and modifications to overcome limitations discovered during this testing phase. Refer below for an analysis of sub-component performance and limitations.

Propaq Model 106 LCD physiological monitor – This unit experienced problems with the CO_2 sensor during hot and cold operation evaluation. AFMEDF recommends operating unit

within manufacturer's temperature specifications (50-104° F). The CO_2 sensor experienced an "out of range" alarm at 15,000 ft. AFMEDF does not consider this a significant failure for the use of the LSTAT by the U.S. Air Force.

IMPACT Model 326 Continuous/ Intermittent Suction Unit (CISU) – This unit experienced excessive recovery times exceeding one hour following cold storage testing. AFMEDF recommends operating unit within manufacturer's temperature specifications. (-20° to 40° C operating and -15° to 40° C storage and shipping)

SurVivaLink Automated External Defibrillator (AED) – This unit had trouble maintaining proper performance of Advanced Cardiac Life Support protocols. The AED, on more than one occasion, failed to deliver a third shock in a three shock series. This particular model of AED was previously assessed by AFMEDF as a stand-alone device for proposed use in the U.S. Air Force aeromedical environment. The manufacturer withdrew the device from testing. **For these reasons, AFMEDF recommends this AED be removed and not to be used in-flight. AFMEDF considers this AED not approved for use in USAF aircraft.**

IVAC MedSystem III Infusion Pump – This infusion pump displayed "air in the line" during the 60 second RD. Channel B alarmed "air in the line" during the 7-second and 1-second RD. However, all alarms cleared upon return to ground level. AFMEDF does not consider these events to put the patient at undo risk. Please be aware that the aforementioned event is possible and assess the patient and infusion pump accordingly.

IMPACT Model 754 "Eagle" Transport Ventilator – During rapid decompression the ventilator alarmed. However, it recovered upon return to ground level. The LCD screen went blank 1.5 hours into humidity testing and stayed blank throughout remainder of test. AFMEDF recommends operating the device when configured as a LSTAT sub-component IAW humidity restrictions set forth by the ventilator manufacturer. Also, a filter/screen inside the flow control valve became blocked by excessive condensation causing the ventilator to fail. A "Failure Code 3 – Total Flow Backup, Check Failure" alarm was displayed preventing the unit from functioning. To clear this problem, the NATO litter and an access panel had to be removed to gain entry into the LSTAT. Once inside the LSTAT, the flow control valve had to be disassembled, cleaned and replaced before the ventilator would function again. It took 40 minutes to finally clear this alarm condition. Specifically, the flow control valve on the ventilator breathing circuit needs to be moved to an area providing rapid access to the filter/ screen. AFMEDF recommends if possible to move this valve assembly to just proximal of the head fairing gas outlet connector. **AFMEDF considers this a single point failure and the LSTAT is not approved for use in USAF aircraft until recommended modifications are made.**

Display and Data Logging Subsystem (DDLS) – During altitude evaluation the secondary display showed episodes of interference (characterized as a sweeping vertical bar) at altitudes above 8,000 ft. However, the device remained functional and the display could be read. AFMEDF recommends monitoring LSTAT sub-components through their respective display screens.

i-Stat Blood Analyzer - The blood analyzer had multiple problems during temperature and humidity evaluations. It is important to note the LSTAT storage compartment for the i-Stat is not insulated against environmental extremes. The unit requires long lead times to recover from environmental extremes. AFMEDF recommends protecting the unit from environmental extremes and operate the unit IAW manufacturer specifications regarding ambient temperature and humidity. [16 to 30° C (61-86° F) operating, -10° to 50° C (14-122° F) transporting and 0 to 65% (min) non-condensing relative humidity]

Power Requirements:

115 VAC ± 10% VAC, 60 Hz ±5 Hz, one phase
108-118 VAC 400 Hz ±7 Hz, one phase
230 VAC ± 10% VAC, 50 Hz ±3 Hz, one phase
25 ±5 VDC
Batteries: Nickel-Cadmium (NiCd), > 30 min., Rechargeable

Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-2000-0027

Product and Manufacturer

SEABROOK MEDICAL SYSTEMS, INC. ECMO-TEMP BLOOD WARMING UNIT, MODEL SMS-3000

Seabrook Medical Systems Inc.
4043 McMann Rd.
Cincinnati, OH 45245-1903

Date Evaluated: June 1998

Description:

The Seabrook Medical Systems, ECMO-TEMP Blood Warming Unit provides a flow of temperature controlled water to a heat exchanger. This heat exchanger is connected in the blood flow path in series between the oxygenator and the patient during an ECMO procedure. The Seabrook provides a means for warming and controlling blood temperature prior to and during perfusion. The Seabrook consists of a plastic reservoir for holding distilled water; a float switch to indicate low water level; a pump for circulating water through an external heat exchanger; a heating element to warm the water; a microprocessor-based electronic control to regulate water temperature; two independent back-up high limit devices to protect the patient and the unit; a water flow indicator to provide visual assurance of proper water flow; two connecting hoses for attachment of the heat exchanger; and a fan for removing heat generated within the unit enclosure. A phone jack marked "Blood Probe" allows connection of a 400 series-type thermistor probe for monitoring and/or controlling blood temperature. The control panel offers two modes of operation: "Water Temp" and "Blood Temp". In the " Water Temp" mode, the operator selects the desired water temperature setpoint and the Seabrook maintains the water at that temperature. In the "Blood Temp" mode, the operator selects the desired blood temperature as measured by the remote probe, and the Seabrook regulates the water temperature to maintain the blood temperature at the setpoint. The "Blood Temp" mode was not evaluated because ECMO team did not require this mode. Audible and visual alarms indicate "Add Water", "Under Setpoint", "Over Setpoint", and "High Limit". Digital displays indicate water temperature, setpoint, and blood temperature (when a probe is connected), in degrees centigrade. The Seabrook operates from 115 VAC/60 Hz power and weighs 24 lbs (dry). The dimensions are 9.75 inches W. X 14 inches H. X 11 inches D.

Summary:

AFMEDF found the Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit to be CONDITIONAL for use on large bodied U.S. Air Force aeromedical evacuation aircraft such as the C-9A, C-130, C-141, etc. Its operation was within expected parameters when subjected to cold and humid environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. Since the Seabrook operated within tolerance during the airborne performance phases of testing it is deemed conditionally acceptable for use. The following requirements apply:

A. Set up and operated by ECMO team members

B. Must be plugged into a Tripplite® Isobar Model IB-4 noise filter and transient voltage surge suppressor.

C. Positioned and secured to the neonatal/pediatric ECMO transport cart.

D. The setpoint temperature must be adjusted if the ambient temperature at the enplaning or deplaning station exceeds 29.5°C (85°F).

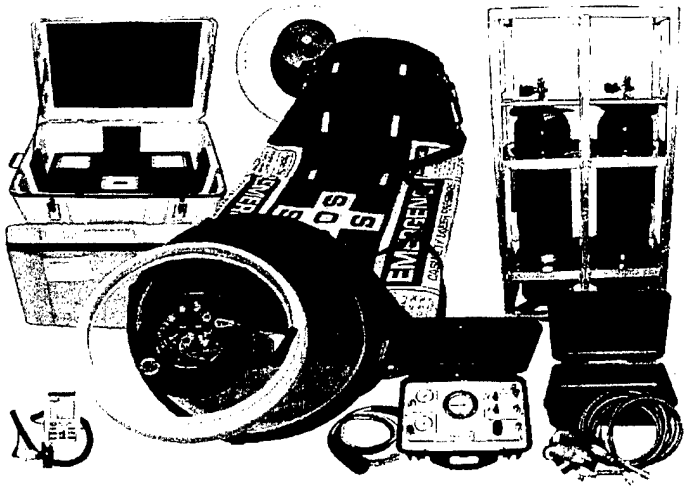
Power Requirements: The Seabrook operates from 115 VAC/60 Hz power

Procurement: Manufacturer

Reference: Technical Report number AFRL-HE-BR-TR-1998-0019

Product and Manufacturer

THE SOS, Ltd., HYPERLITE, EMERGENCY EVACUATION HYPERBARIC STRETCHER, MODEL 24/88/SAT/70



SOS, Ltd.,
612 Watford Way
London NW7 3JH
England
Telephone: +44 (0) 20 8959 8959

Website: www.hyperlite.co.uk

Date Evaluated: September 2000

Description:

The SOS, Ltd., Hyperlite, Emergency Evacuation Hyperbaric Stretcher (EEHS), model 24/88/SAT/70 is a portable and collapsible hyperbaric chamber that can be used as a means of transporting personnel suffering from decompression sickness or gas embolism to a recompression treatment facility. The Hyperlite provides an easily transported means of emergency evacuation of a casualty while under pressure from the diving accident site to land based/ hospital hyperbaric facilities. The Hyperlite is a deployable unit and is designed for manual transport while pressurized with one occupant. The Hyperlite can be pressurized and ventilated with compressed air. The Hyperlite incorporates a means of observing and administering oxygen to the occupant while pressurized.

The Hyperlite comes equipped with a flexible pressure chamber, which can withstand maximum working pressures up to 69 Feet Seawater or 30.5 pounds per square inch. The Hyperlite has two full diameter, self-sealing acrylic end domes. Once the end domes are inserted into the ends of the pressure chamber and pressure is applied the end domes push outward against the pressure chamber creating a seal. The end domes also provide access via a medication port at the head end and access ports for communications, patient monitoring, oxygen administration and monitoring, and a means to pressurize the pressure chamber. The Hyperlite Control Box has a manifold to distribute oxygen to the patient and compressed air to the pressure chamber. The Hyperlite control box is also equipped with two gauges to monitor system pressure for air and oxygen. There is also a depth gauge indicator. Mine Safety Appliances, Co., Model 3000 Oxygen Monitor displays oxygen concentrations inside the pressure chamber. The Built In Breathing System (BIBS) consists of an Amron International Diving Supply Inc., Scott Divers Inhalator Mask, Pressur-Vak II series, Model 803139. The Pressur-Vak II is designed to deliver patient oxygen in a hyperbaric environment. It eliminates oxygen build up by dumping exhaled gases directly out of the chamber. A David-Clark, Inc., Wired Headset System model 200, modified with PN WRC-HYBICS, is used to communicate with the patient inside the pressure chamber and support personnel outside the pressure chamber. Throughout testing the Hyperlite operated off one or more S-80 (steel/80 cubic feet of air) compressed air cylinders manufactured by Catalina. The Hyperlite weighs approximately 123.76 lbs. Its dimensions are Length 85 inches with a Diameter of 23 inches. Internal pressure chamber volume is 18 cubic feet. The transport cases are approximately 29 inches wide X by 25 inches deep X 29 inches

wide X 15 inches deep X 26 inches high. The complete Hyperlite system with all components to include storage containers, dive tanks, etc. weighs approximately 296 lbs.

Summary:

AFMEDF found the SOS, Ltd., Hyperlite, Emergency Evacuation Hyperbaric Stretcher, Model 24/88/SAT/70 (S/N: 0000008994); Control Box Model Z08 (S/N: 005); David-Clark, Inc., Wired Headset System modified with kit # WRC-HYBICS; Amron International Diving Supply Inc., SCOTT® Pressur-Vak II Inhalator with Overboard Discharge, Model 803139-00 (P/N: 803152-02); Catalina S-80 (steel/80 cubic feet of air) dive tanks DOT number 3AL3000AS194479M4002 02A99 S80; Mine Safety Appliances, Model 3000 Oxygen Monitor; and patient comfort pad ACCEPTABLE for use during all phases of flight on all USAF aircraft (including fixed and rotary wing) with the exception of USAF Tanker aircraft. Explosive vapor testing of the David-Clark, Inc., Wired Headset System (modified with kit # WRC-HYBICS) and the Mine Safety Appliances, Model 3000 Oxygen Monitor was not performed. Approval onboard USAF Tanker aircraft will be granted upon successful testing of Hyperlite's electronic subcomponents requiring explosive vapor testing. The following comments and recommendations apply to the Hyperlite, Emergency Evacuation Hyperbaric Stretcher and its subsystems/components while in the aeromedical evacuation environment:

A. Request a secondary method for securing oxygen tanks to the Hyperlite pressure chamber during manual carries.

B. Due to the Hyperlite's size be aware of placement in all aeromedical aircraft to allow maximum observation of the patient and to prevent obstructing aircraft emergency exits.

C. The Mine Safety Appliances, Co., Model 3000 Oxygen Monitor and the David-Clark, Inc., Wired Headset System, require 9-volt batteries for power. Operators must ensure adequate battery support to accomplish the mission.

D. To aid ease in transporting a patient inside the Hyperlite, one additional carrying strap with two handles, placed at the mid-section must be included.

E. Aircrew members and Hyperlite operators need to be vigilant in regard to pressure chamber safety, internal pressure monitoring, and compressed gas supply (air and oxygen) consumption. AFMEDF recommends descent and ascent absolute stops at 10, 15, and 20 FSW to assess patient comfort level and ability to clear ears. AFMEDF also recommends operation of Hyperlite only under the direct supervision of a healthcare provider with training in hyperbaric medicine.

F. The Hyperlite Control Box, Model Z08 (S/N: 005) should be secured to the top of the chamber to allow visual monitoring of gauges in flight by operators. If unable to secure to chamber, an alternative position would be to mount directly to aircraft floor with cargo strap or web seats with a seatbelt.

G. To secure chamber to aircraft floor, AFMEDF requires six "D" rings and three standard cargo tie-down straps running across the diameter (both ends and mid-section) and

around the ends in front of the Hyperlite end domes. See Appendix "B & C" for illustration of Hyperlite securing procedure.

H. End dome cargo tie-down straps must be tightened in unison. Cargo strap ratchets must be on opposite sides of EEHS tube. End dome cargo tie-down straps should be snug over edges of EEHS but not too tightly winched down. Over tightening can cause tears to EEHS outer rubberized exterior, which would require repair post mission.

I. AFMEDF recommends a padded mattress with pass-through straps to assist in loading the patient into the pressure chamber and aid in the patient's comfort. This mattress will isolate the patient from the affects of vibration conducted through the pressure chamber.

J. AFMEDF recommends dive tanks be inspected/serviced by properly trained personnel (i.e. scuba shop) so that tanks are in compliance with Department of Transportation (DOT) guidelines and safety standards.

K. Caution must be used when installing acrylic end domes. Manual traction must be maintained simultaneously on both domes until initial pressure seal is obtained. Lack of attention to this may cause dome to fall inward causing injury to patient. It may also cause excessive loss of pressurized gas.

L. Routine briefing to patients should include special instructions on ear clearing to prevent barotrauma during descent. Few people have experience clearing ears while lying supine. Tipping the head backward with a small back/neck arching movement worked satisfactorily for test subjects. Special instructions must also include not holding breath or valsalving to prevent pneumo-barotrauma during ascent.

M. Recommend patient comfort pad dimensions be increased to 176 inches by 24 inches. Thickness of pad must be increased by 50% to reduce vibration and thermal conduction during aeromedical evacuation. Recommend comfort pad have 6 hand-holds along sides to allow for patient movement. Recommend straps at both ends of pad to allow pad to be pulled through chamber to aid in patient positioning. Recommend patient securing straps be added to aid in transporting patient while on mattress alone.

N. SOS Limited has proposed a secondary depth gauge to be used inside the EEHS during treatment dives. As of the publication of this technical report, a depth gauge has not been evaluated by AFMEDF. A mounting bracket to secure the proposed gauge to the inside of the foot- end dome needs to be designed and tested.

O. Direct exposure to sunlight will cause inside temperature of EEHS to significantly increase. Frequent assessment of EEHS occupant must be done during extreme environmental exposure conditions.

P. Some disassembly/configuration of the airframe internal cargo bay components (auxiliary fuel tank and ammo tray) may be necessary on the USAF UH-60 helicopter to accommodate the EEHS.

Q. The Amron International Diving Supply Inc., SCOTT® Divers Inhalator Mask, Pressur-Vak II series, Model 803139 should be inspected and serviced per manufacturer's instructions.

Power Requirements:

The Mine Safety Appliances, Co., Model 3000 Oxygen Monitor and the David-Clark, Inc., Wired Headset System, each require 9-Volt batteries for power.

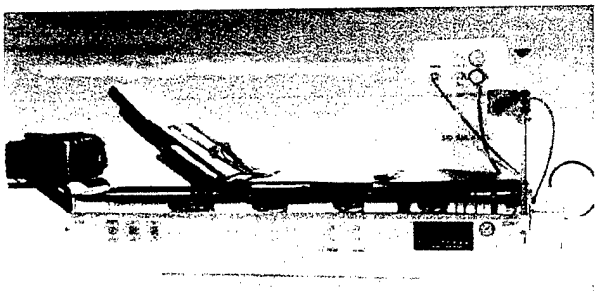
Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-2001-0069

Product and Manufacturer

SPECTRUM AEROMED, SPECTRUM 500-LP (MILITARY VERSION) MODEL 2500-US

Spectrum Aeromed, Inc.
RT. 2 Box 99
Wheaton, MN 56596



Date Evaluated: September 1994

Description:

The Spectrum 500-LP Air Ambulance Life Support System is a fully modular, quick change unit for use in both fixed and rotary wing aircraft. The unit automatically locks into place onto a multi-purpose seat rail adapter when placed into position. The unit stretcher is covered with Staph-Chek vinyl over a two-inch pad. The unit loading system attaches directly to the unit and is adjustable to various aircraft. Outlets on the overhead console and base unit provide access to oxygen, medical air, and vacuum. The unit also has a heavy-duty telescoping IV pole with four hangers holding up to sixteen pounds of fluid.

Summary:

The Spectrum 500-LP (military version) model 2500-US, was found to be CONDITIONAL for use in the aeromedical evacuation environment provided all modifications to pass EMI radiation limits and vibration curves, have been met. Airborne feasibility was performed on a C-21 Lear jet and is compatible with the aircraft electrical system. To operate the unit on other aeromedical evacuation aircraft, specialized securing adapters are required. These adapters can be obtained through the manufacturer. During this evaluation the following was observed:

1. Due to interior height restrictions, performing Cardiopulmonary Resuscitation (CPR) may prove difficult. Full arm extension is not possible when performing cardiac compressions.

2. Extreme caution should be taken when working within close proximity or passing in front of the base unit. There is a possibility of breaking or dislodging flowmeters, suction devices, and power cords from auxiliary life support equipment.

3. When using more than one Spectrum 500-LP (Military Version), Model Number 2500-US, space limitations will hamper accessibility to egress exits by medical crew.

4. Because of the close proximity of aircraft's seats, visualization of base unit gauges, flowmeters, and suction devices may be difficult.

5. Heat from the metal frame around the light housing on the overhead console may cause a burn injury.

Power Requirements:

Unit operates using aircraft power; provides 115 VAC/60 Hz electrical power supplied by two 350 watt 28 VDC inverters.

Procurement: Manufacturer

Reference: Technical Report number: AL/CF-TR-1996-0053

Product and Manufacturer

STÖCKERT SHILEY MULTIFLOW ROLLER PUMP MODULE, 10H SERIES, MODEL 10-10-00

Date Evaluated: June 1997

Description:

The Stöckert-Shiley, Multiflow Roller Pump is a precision peristalic pump. It is an integral component of the Neonatal/Pediatric ECMO Transport System. The roller pump is plugged into a series bladder box, then into a modified Tripplite Isobar, then into a Topaz uninterruptible power supply (UPS), then into 115 VAC/60 Hz aircraft power. The roller pump accommodates a wide range of flow rates using different tubing diameters together with the different size tubing inserts available for the monitor. The roller pump is capable of displaying both revolutions per minute and flow rates in LPM. Only LPM should be displayed during an aeromedical evacuation ECMO Transport.

Summary:

AFMEDF found the Stöckert-Shiley, Multiflow Roller Pump, 10H Series, Model 10-10-00 to be CONDITIONAL with the following requirements:

A. The maximum flowrate authorized is 5.82 LPM since the pump had electromagnetic interference (EMI) when the flowrate was set above 5.82 LPM.

B. Plugged in series into the Venous Controller/Blood Pump Regulator ("bladder box"), then into 115 VAC/60 Hz aircraft power.

   Example: Roller Pump → Bladder Box → Modified Tripplite Isobar → 115 VAC/60 Hz aircraft power.

C. Must be plugged into a modified Tripplite Isobar Model IB-4 noise filter and transient voltage surge suppresser to reduce EMI below limits.

D. Must be plugged into a Topaz Uninterruptible Power Supply to provide battery support

E. Flowrate set at 5.82 LPM or less

Power Requirements: The unit operates on 115 VAC/60 Hz aircraft power

Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-1998-0080

Power

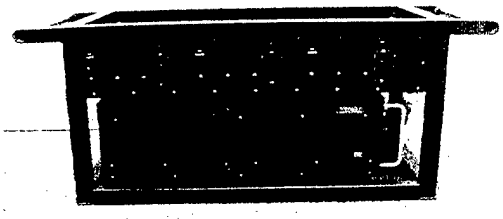
AVIONIC INSTRUMENTS FREQUENCY CONVERTER

UNITRON, INC., MODEL PS-95-448-1 MEDI-VAC PORTABLE POWER SYSTEM

Product and Manufacturer

AVIONIC INSTRUMENTS FREQUENCY CONVERTER
Model 4B3500-1A-MV-735/4B3500-1A-MV-1564,
P/N 1-002-0102-0735/1-002-0102-1564

Avionic Instruments Inc.
1414 Randolph Avenue
Avenel, NJ 07001
Telephone (201) 388-3500



Date Evaluated: May 1996

Description:

The Avionic Instruments, Inc. Frequency Converter Model 4B3500-1A-MV-735 is an electronic device that converts aircraft 400 Hz, three phase, 115-200 Vrms into 60 Hz, single phase, 115 Vrms. It employs patented circuitry and proven technology to provide up to 3500 watts of power. The efficiency of the unit is 80% or greater under normal operating conditions. The unit is designed to operate at 3500 watts fully loaded (115 volts @ power factor 0.8 leading to 0.75 lagging). The Frequency Converter is designed to withstand extreme shock, vibration, acceleration, altitude, temperature, short circuit, and overload conditions without damage.

Summary:

AFMEDF found the Avionic Instruments, Inc. Frequency Converter Model 4B3500-1A-MV-735/4B3500-1A-MV-1564 to be ACCEPTABLE for use on all U.S. Air Force aeromedical evacuation aircraft during all phases of flight. It proved to be extremely easy to setup and operate and met all of the standards and limits outlined for aeromedical evacuation equipment. The Frequency Converter operated within expected parameters when subjected to environmental extremes and simulated cabin altitudes.

Power Requirements: 115 VAC/400 Hz (aircraft supplied power)

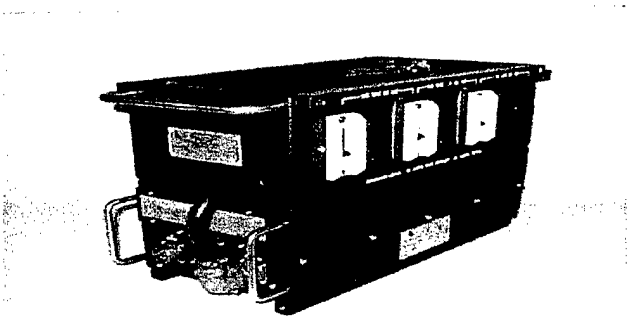
Procurement: Manufacturer

Reference: Technical Report number: AL/CF-TR-1996-0057

Product and Manufacturer

UNITRON, INC., MODEL PS-95-448-1 MEDI-VAC PORTABLE POWER SYSTEM

Unitron Incorporated
10925 Miller Road
Dallas, TX 75238
Telephone: (800) 527-1279



Date Evaluated: December 1998

Description:

The Unitron, Inc., Model PS-95-448-1, Medi-Vac Portable Power System is a portable frequency converter that converts 400 Hz, 3-phase, 115/200 VAC aircraft power into 60 Hz, single-phase, 115 VAC power distribution used to operate medical equipment. The unit operates on 115 VAC/400 Hz power. The unit weights approximately 51.16 lbs and is 10.5 inches W. X 12.75 inches H. X 23 inches D.

Summary:

AFMEDF found the Unitron, Inc., Model PS-95-448-1, Medi-Vac Portable Power System to be ACCEPTABLE for use on all USAF aircraft (including small and large body, fixed and rotary wing) while operating on 115 VAC/400 Hz power. Its operation was within expected parameters when subjected to electromagnetic interference (EMI); environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. Changes in structural components were necessitated due to component improvements based on vibration testing and human factor analysis.

Power Requirements: The unit operates on 115 VAC/400 Hz power.

Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-1998-0122

Pulse Oximeters

- BCI INTERNATIONAL 3303 OXIMETER
- BCI INTERNATIONAL 3304 OXIMETER
- OHMEDA, INC., MODEL 3800 PULSE OXIMETER

Product and Manufacturer

BCI INTERNATIONAL 3303 OXIMETER

BCI International
W238 N 1650 Rockwood Drive
Waukesha, WI 53188-1199
(262) 542-3100

Date Evaluated: June 1997

Description:

The BCI 3303 is a portable pulse oximeter that measures SpO_2 and pulse through the use of either a disposable probe or a reusable finger probe. SpO_2 is defined as the arterial O_2 saturation measured by a pulse Doppler technique. The disposable probe comes in a variety of sizes to fit adults to neonates and may be used at various points on the patient's body. The rechargeable internal battery will last 12 hours nominal use without recharging. A 115 VAC/60 Hz power supply is used to either recharge the battery or operate the unit continuously while the battery is trickle charged. Any time the 115 VAC/60 Hz power supply is connected, the battery is maintained even if the 3303 is turned off.

The 3303 has SpO_2 and pulse rate numeric LED displays, an eight-segment LED pulse strength bar graph, probe light, battery light, and alarm-silenced light. There is a power light that indicates the 115 VAC/60 Hz power supply is attached. The charging light is yellow when the battery is fast charging and off when the battery is fully charged.

The 3303 has controls for on, off/standby, volume alarm, volume pulse, I.D. clear, volume up and down, alarm silence, and alarm select. The operator can set the alarm and pulse volume to individual preference. The "I.D. clear" is used to reference multiple patients each time the button is pressed, or the stored patient data can be erased and the patient counter reset.

The 3303 has three modes of operation: Clinician, Home-use, and Sleep Study. The Clinician mode is for use by health care professionals. The Home-use mode permits the home-use caregiver to monitor a patient at home and also record the data for later analysis, and the Sleep Study mode allows the health care professional to record sleep study data for later analysis on a PC computer.

General Specifications Of The BCI 3303 Pulse Oximeter

Size	84 mm (3.3 in)	184 mm (7.25 in)	47 mm (1.85 in)
Weight	19 ounces (539 grams)		
SpO_2 range	0% - 100%		
Pulse Rate	30 - 254 BPM		

Summary:

AFMEDF found the BCI 3303 to be CONDITIONAL for use on all U.S. Air Force aeromedical evacuation aircraft while operating on battery power. The unit should be used strictly as a trend indication device. The following recommendations and operational restrictions accompany the airworthiness approval of the 3303 system.

A. **The AC power supplies for the BCI 3303 and 3304 are NOT INTERCHANGEABLE.** The power plugs on the pulse oximeter are the same, but the AC power supplies are not. Be sure you have the right AC power supply for the unit. Destruction of the 3303 or the power supply will result from use of the improper supply.

B. When used in-flight to monitor a patient the 3303 should be operated only on battery power.

C. The power supply may be used in-flight to charge the battery, but not while monitoring the patient.

D. The unit readout values may drift up and down at altitudes above 6,500 ft. Correcting this drift may involve changing the averaging factors for SpO_2 and pulse. This drift may be corrected by following the instructions in the operations manual.

E. The 3303 failed parts of the EMI emissions and susceptibility testing. These failures will not endanger the patient or aircraft. The failures should be noted but they are not considered serious enough to ban the use of the 3303.

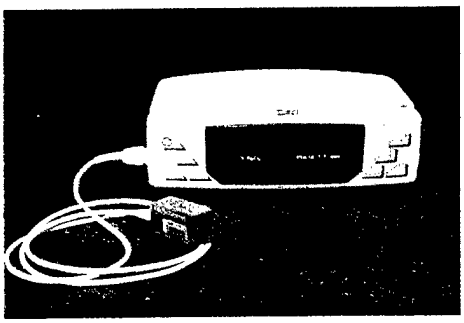
Power Requirements: 115 VAC/60 Hz and an internal rechargeable battery pack

Procurement: Manufacturer

Reference: Technical Report number: AL/CF-TR-1998-0015

Product and Manufacturer

BCI INTERNATIONAL 3304 OXIMETER



BCI International
W238 N 1650 Rockwood Drive
Waukesha, WI 53188-1199
Telephone: (262) 542-3100

Date Evaluated: June 1997

Description:

The 3304 is a portable pulse oximeter that measures SpO_2 and pulse through the use of either a disposable probe or a reusable finger probe. SpO_2 is defined as the arterial O_2 saturation measured by a pulse Doppler technique The disposable probe comes in a variety of sizes to fit adults to neonates and may be used at various points on the patient's body. The rechargeable internal battery lasts 4.5 hours nominal use without recharging. A 115 VAC/60 power supply is used to either recharge the battery or operate the unit continuously while the battery is trickle charged. Any time the 115 VAC/60Hz power supply is connected, the battery is maintained even if the 3304 is turned off.

The 3304 has SpO_2 and pulse rate numeric LED displays, an eight-segment LED pulse strength bar graph, artifact light, search light, probe light, low battery light, and alarm silenced light. There is a power light that indicates the 115 VAC/60Hz power supply is attached and the 3304's battery is charging.

The 3304 has controls for on/off, alarm volume, pulse volume, volume up and down, I.D. clear, alarm silence, and alarm select. The operator can set alarm and pulse volume to individual preference. The "I.D. clear" is used to reference multiple patients each time the button is pressed, or the stored patient data can be erased and the patient counter reset.

The 3304 has two modes of operation: Clinician and Home-use. The Clinician mode is for use by health care professionals, the Home-use mode permits the home-use caregiver to monitor a patient at home and also record the data for later analysis.

General Specifications of the BCI 3304 Pulse Oximeter

Size	216 mm (8.5 in)	82 mm (3.24 in)	140 mm (5.5 in)
Weight	850 grams (30 ounces)		
SpO_2 Range	0% - 100%		
Pulse Rate	30 - 254 BPM		

Summary:

Testing and evaluation found the BCI 3304 to be CONDITIONAL for use on all U.S. Air Force aeromedical evacuation aircraft. The unit should be used strictly as a trend indication device. Several problems noted during vibration testing should be corrected by the company. The following recommendations and warnings accompany the airworthiness approval of the 3304 system.

A. **The AC power supplies for the BCI 3303 and 3304 are NOT INTERCHANGEABLE.** The power plugs on the pulse oximeters are the same, but the power supplies are not. Be sure you have the right power supply for the unit. Destruction of the 3304 or the power supply will result from use of the wrong supply.

B. The unit may fail to operate properly when exposed to impulse excitations e.g. radar sweeps. The unit should recover as soon as the signal strength decreases.

C. The unit readout values may drift up and down at altitudes above 6,500 ft. The correction of this may involve changing the averaging factors for SpO_2 and pulse. This drift may be corrected by following the instructions in the operations manual.

Power Requirements: 115 VAC/60 Hz and internal rechargeable battery

Procurement: Manufacturer

Reference: Technical Report number: AL/CF-TR-1998-0014

Product and Manufacturer

OHMEDA, INC., MODEL 3800 PULSE OXIMETER

OHMEDA, INC.
1315 West Century Drive
Louisville, CO 80027
Telephone: (303) 666-7001

Date Evaluated: June 1998

Description:

The Ohmeda, Inc. model 3800, pulse oximeter is a non-invasive, arterial oxygen saturation and pulse monitor. Specific components of the model 3800, pulse oximeter included the model 3800, pulse oximeter basic unit and flip tip sensor (PN 6051-0000-112). The unit operates on 100/120 VAC/60 Hz and an internal rechargeable battery pack. The unit weighs 2.23 kg or 4.92 lb. Dimensions are 9.53 inches W. X 3.7 inches H. X 8.86 inches D.

Summary:

AFMEDF found the Ohmeda, Inc., model 3800 pulse oximeter to be ACCEPTABLE for use on all U.S. Air Force aeromedical evacuation aircraft while operating on 115 VAC/60 Hz or battery power. However, during susceptibility testing the unit experienced an increase in pulse rate from 74-83 bpm and an SpO_2 increase from 89-94 percent between a frequency range of 50 Hz – 0.2 kHz. To validate the unit's operation in this frequency range assessment was done during airborne performance testing. The unit operated IAW manufacturer's specifications with no unit degradation noted. With the above validation complete, further evaluation of the unit's operation was within expected parameters when subjected to environmental extremes, simulated cabin altitude and did not produce a hazard to patient or crew during rapid decompression.
The following recommendations apply:

A. As with any pulse oximeter, patient movement or vibration of the unit may cause pulse rate and SpO_2 to be erratic and unreadable; therefore, it should be used for trend analysis.

Note: Audible alarms cannot be heard in high noise environments when hearing protection is used. Visually monitor unit during flight.

Power Requirements: The unit operates using 115 VAC/60 Hz and internal battery power.

Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-1998-0022

Respiratory

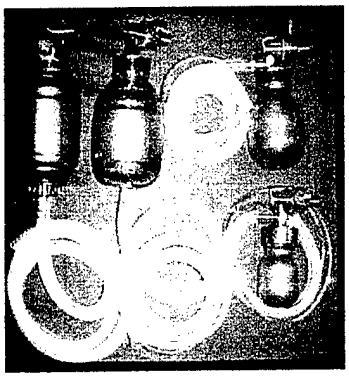
- VITAL SIGNS INC. MODELS VITAL BLUE (ADULT) & CODE BLUE (ADULT), PEDI BLUE (CHILD), AND BABY BLUE (INFANT) MANUAL RESUSCITATORS

Product and Manufacturer

VITAL SIGNS INC. MODELS VITAL BLUE (ADULT) & CODE BLUE (ADULT), PEDI BLUE (CHILD), AND BABY BLUE (INFANT) MANUAL RESUSCITATORS

Vital Signs Inc.
20 Campus Road
Totowa, NJ 07512

Telephone: (800) 932-0760
Fax: (973) 790-3307



Date Evaluated: January 1999

Description:

The devices are hand-held lightweight, manual resuscitators. They provide clinicians a way to maintain ventilatory support for patients with life-threatening airway disorders. The resuscitators operate by manually squeezing the plastic reservoir bag to create a positive airflow to expand the patient's lungs

Summary:

AFMEDF found the Vital Signs, Inc., Models: Vital Blue (Adult) & Code Blue (Adult), Pedi-Blue (Child), and Baby Blue (Infant) Manual Resuscitators to be ACCEPTABLE for use on all U.S. Air Force aeromedical evacuation aircraft. Their operation was within expected parameters under environmental extremes and simulated cabin altitudes. They did not produce a hazard to patient or crew during simulated rapid decompression testing.

Power Requirements: Oxygen source (medical grade, 100%)

Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-2000-0030

Securing Devices

- IMPACT INSTRUMENTATIONS BRACKET, MOUNTING, STANCION

- SPECIAL EMERGENCY EVACUATION DEVICE (SMEED)

Product and Manufacturer

IMPACT INSTRUMENTATIONS BRACKET, MOUNTING, STANCHION PART # 820-0077-00
IMPACT Instrumentations, Inc.
27 Fairchild Place, P.O. Box 508
West Caldwell, NJ 07006
Telephone (201) 882-1212

Date Evaluated: January 2001

Description:

The Impact Instrumentations Bracket, Mounting, Stanchion is a universal bracket designed to house and secure medical equipment to aircraft stanchion poles. Medical equipment is secured onto the bracket using bayonet fittings that allow the item to insert into the mounting receptacles of the mounting bracket. Medical equipment is locked in place by fully rotating the black friction finder lever to its full extent to completely lock down the equipment to the bracket bayonet mounts

Summary:

AFMEDF found the mounting bracket ACCEPTABLE for use during all phases of flight on all USAF fixed wing aircraft. The following comments and recommendations apply to the Impact Instruments device:

A. Recommend bracket include a sticker indicating proper positioning for mounting. Example, " ↑ THIS SIDE UP" to aid in proper position for vertical stanchion mounting. Some aeromedical evacuation crewmembers attempted to mount bracket with bayonet mount pointing towards the aircraft floor.

B. The nylon strap used to secure the bracket showed some wear and tear as a result of testing. Consultation with the AFRL's software fabrication lab technician led to the following recommendation. The webbing strap used should be doubled in terms of current thickness. This will extend the life of the strap due to wear and tear during use. A thicker strap did not bind the ratchet or over fill its spindle. The nylon strap can be replaced by minimal disassembly of the ratchet from the bracket main body and a new strap secured by stitching overlay by parachute shop personnel. Sustainment considerations should include identification of nylon strap nomenclature and thickness so replacement material can be easily procured.

C. Recommend adjustable securing plate width in the Y axis be increased form 2 inches to 2 ¼ inches to accommodate stanchion poles on multiple aircraft.

D. AFMEDF discovered when mounting the bracket onto a stanchion pole, metal-to-metal contact frequently caused paint to come off C-9A stanchion poles. Recommend bracket have the small plastic friction pad on sliding aluminum plate increased in size to cover all of

potential stanchion contact surface. Add this material to stanchion contact surface of ratchet contact plate to prevent damage to stanchion poles and increase gripping capability.

E. AECMs must secure bracket where operation and release of ratchet will not be obstructed by interior aspects of aircraft systems or surrounding medical equipment

F. Bracket was successfully mounted on Evans overhead seat back support bar of C-130 aircraft. The bracket should be positioned flat across the top of the seat support bracket and not at an angle. However, a warning should be noted not to let personnel sit directly under the bracket when equipment is secured to it. Falling equipment would likely strike/land on anyone sitting directly underneath the bracket. The 754 ventilator would have to be secured in the non-rotating bayonet mount in this configuration. This limits AECM observation of LCD display while seated since angling the 754 ventilator on the pivot mount is not possible. A litter strap passed through the ventilator carrying handle is recommended in-flight. Securing the bracket so that only the nylon securing strap passes over the top of the seat back support bar is not recommended. The bracket came loose in flight in this configuration when the 754 ventilator and AC power supply were mounted to it. It did not strike the floor, but did swing downward and would have bumped someone's head had anyone been sitting directly underneath in the Evans seat.

G. C-9A aircraft bracket securing led to following recommendation. Do not attempt to mount bracket on lower half of foot litter stanchion pole. It has a convex shape and any downward slippage of bracket will cause it to give way and fall towards the floor. An excellent securing location was the horizontal cantilever arm. However, mounting the ventilator at the patient's foot cantilever arm may be the preferred location when the patient is supine.

H. AECMs should be made aware of the need to fully rotate the black friction finder lever to its full extent to completely lock down the ventilator and converter to the bracket bayonet mounts. Partial rotation of the levers will not fully seat the bayonet into the mounting receptacle.

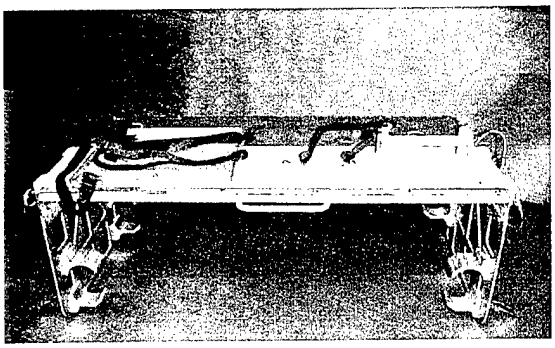
Power Requirements: None

Procurement: Manufacturer

Product and Manufacturer

SPECIAL EMERGENCY EVACUATION DEVICE (SMEED), MODEL 1X

United States Army Institute of Surgical Research
3400 Rawley Chambers Blvd.
Fort Sam Houston, TX 78234
(210) 916-5391



Date Evaluated: December 2000

Description:

The Special Emergency Evacuation Device (SMEED) is a portable securing device designed to secure medical equipment at the foot-end of an occupied NATO litter while transporting a patient in the AE environment. The device was designed to secure medical equipment and not to exceed a carrying load of 24.20 lbs.

Summary:

1. The test and evaluation of the Special Emergency Evacuation Device, model 1X has been completed. AFMEDF found this device ACCEPTABLE for use during all phases of flight on all USAF aircraft (including fixed and rotary wing).

2. The following comments and recommendations apply to the SMEED:

A. When the SMEED is mounted on a standard NATO litter and has medical equipment secured to it (such as the Propaq 206, IVAC MedSystem III, and ventilator) care must be taken when loading into and out of aircraft litter tiers. Stirrups on above litter can strike medical equipment causing accidental damage. Litter bearers should be briefed on cautions in this regard. AFMEDF recommends that the Propaq monitor display screen be positioned to face the patient during onload and offload to minimize risk of striking the screen during patient litter hand carries.

B. Litter stirrups of NATO litters placed above the mounted SMEED may impede rotation of the swivel tray in some aircraft litter load configurations such as C-130 centerline litter tiers and C-9A Special Care Area using all four litter tiers. Raising the litter handle of the litter above the SMEED Platform will allow free swiveling of medical equipment into the desired in-flight position. Litter above can then be lowered and secured. Aeromedical Evacuation crews should configure the SMEED into the desired configuration before loading the patient onboard USAF aircraft if at all possible to minimize patient loading time. Reconfiguration of the SMEED onboard aircraft is easily accomplished if needed.

C. AFMEDF recommends SMEED be modified with four additional holes to allow swivel tray to lock at 45 degree increments in addition to the 90 degree settings currently employed.

D. Recommend spare locking pin be included and secured onto the SMEED.

Power Requirements: None

Procurement: United States Army Institute of Surgical Research

Suction Devices

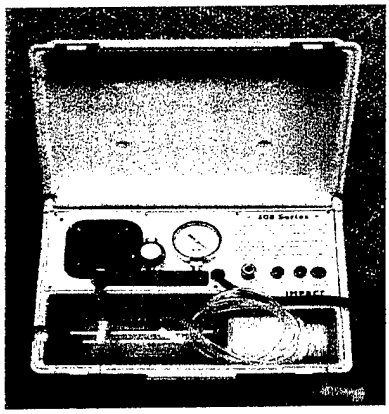
- IMPACT 308ME13 CONTINUOUS SUCTION UNIT

- IMPACT 326M INTERMITTENT/CONTINUOUS OROPHARYNGEAL/TRACHEAL SUCTION APPARATUS

- LAERDAL MEDICAL CORPORATION, LAERDAL SUCTION UNIT (LSU) 2000/MIL-VAC SUCTION UNIT AND TRANSFORMER/RECTIFIER CATALOG No. 791700

Product and Manufacturer

IMPACT 308ME13 CONTINUOUS SUCTION UNIT



IMPACT Instrumentation, Inc.
P.O. Box 508
West Caldwell, NJ 07006
Telephone (201) 882-1212

Date Evaluated: January 1997

Description:

The IMPACT Instrumentation, Inc., Continuous Oropharyngeal Tracheal Suction, model 308ME13 is a portable self-contained, general purpose, medical suction apparatus designed for removing secretions from the upper airway during oropharyngeal and/or tracheal suctioning.

Summary:

AFMEDF found the IMPACT Instruments, Inc. IMPACT 308M to be ACCEPTABLE for use on all U.S. Air Force aeromedical evacuation aircraft while operating on 115 VAC/60-400 Hz or battery power with the recommendations listed below. Its operation was within expected parameters when it was subjected to environmental extremes and simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. The following recommendations apply:

A. The Specification Sheet, Page 6-1, from the 308M Instruction Manual still reads that the unit can only run for 27 minutes/hour when using 117 VAC External Power. The Specification Sheet should be changed to reflect current model's ability to operate continuously in-flight without any time constraints.

B. When subjected to our vibration curves the IMPACT 308ME13's gauge experienced violent oscillations when the vacuum output was set to maximum (22 inches of Hg). However, oscillations subside, when the unit's output is set to 20 inches of Hg. According to Emergency Care Research Institute (ECRI) guidelines, the unit's output must reach a level of at least 400 mmHg (15.75 inches Hg) for oropharyngeal suctioning. Therefore, our office found this unit to be acceptable for use.

Power Requirements:

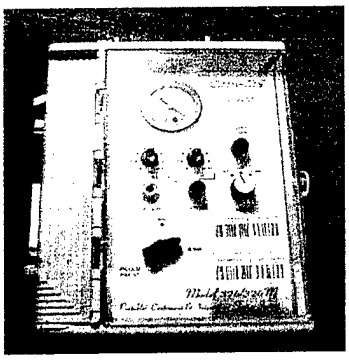
115 VAC/60-400 Hz, external 12 VDC, and internal rechargeable battery pack.

Procurement: Manufacturer

Reference: Technical Report number: AL/CF-TR-1998-0010

Product and Manufacturer

IMPACT 326M INTERMITTENT/CONTINUOUS OROPHARYNGEAL/TRACHEAL SUCTION APPARATUS



IMPACT Instrumentation, Inc.
P.O. Box 508
West Caldwell, NJ 07006
Telephone (201) 882-1212

Date Evaluated: January 1997

Description:

The IMPACT Instrumentation, Inc., Continuous Oropharyngeal Tracheal Suction, model 326 is a portable self-contained, general purpose, medical suction apparatus designed for removing secretions from the upper airway during oropharyngeal and/or tracheal suctioning.

Summary:

AFMEDF found the IMPACT Instruments, Inc. IMPACT 326M to be ACCEPTABLE for use on all U.S. Air Force aeromedical evacuation aircraft while operating on 115 VAC/60-400 Hz, 11-30 VDC or battery power with the recommendations listed below. Its operation was within expected parameters when it was subjected to environmental extremes and simulated cabin altitudes, and did not produce a hazard to patient or crew during simulated rapid decompression

Power Requirements:

115 VAC/60-400 Hz, external 1-30 VDC, and internal rechargeable battery pack.

Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-1998-0018

Product and Manufacturer

LAERDAL MEDICAL CORPORATION, LAERDAL SUCTION UNIT (LSU) 2000/MIL-VAC SUCTION UNIT AND TRANSFORMER/RECTIFIER CATALOG No. 791700

Laerdal Medical Corporation
P.O. Box 190
One Labriola Court
Armonk, N.Y. 10504

Telephone: (800) 431-1055

Date Evaluated: September 1997

Description:

The Laerdal Suction Unit (LSU) 2000/MIL-Vac is a portable oropharyngeal/tracheal suction unit that is self-contained in a hard plastic case. It incorporates an internal rechargeable battery. The LSU is designed to be efficient and user friendly with a minimum of controls and has a 1000 ml. collection container with tubing storage incorporated in the top of the container.

Summary:

AFMEDF found the MIL-Vac and Transformer/Rectifier ACCEPTABLE for use on all Air Force aircraft during all phases of flight while operating from battery power, 28 VDC, or the Transformer/Rectifier (115 VAC/60 Hz).

Power Requirements:

Suitable power sources include the Laerdal Transformer/Rectifier Cat. No. 791700 which operates from 115 VAC/60 Hz or 28 VDC through the 12-28 VDC power cord. In order to use DC power on USAF aircraft, a Hubbell Twist-Lock plug, Catalog Number 7545C or equivalent is required to be installed. The Laerdal Transformer/Rectifier converts 115 VAC/60 Hz line voltage to low voltage DC. It operates the MIL-Vac and charges the internal battery.
The Mascot Electronic A/S power supply (battery charger) converts 115 VAC/60 Hz line voltage to low voltage DC to charge the internal battery.

Procurement: Manufacturer

Reference: Technical Report number: AL/CF-TR-1997-0083

Ventilators

- BIRD PRODUCTS, CORP. BIRD AVIAN PORTABLE VENTILATOR (MILITARY VERSION) MODEL 15300

- BIO-MED DEVICES MVP-10 NEONATAL/PEDIATRIC VENTILATOR

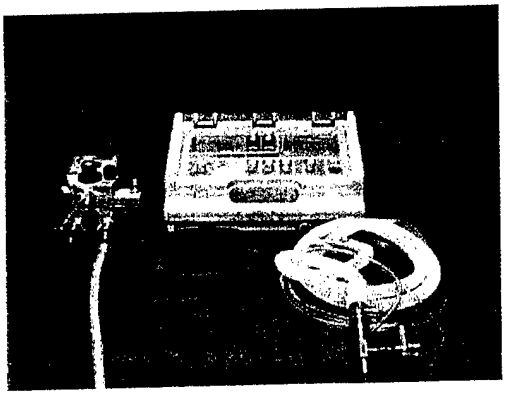
- IMPACT INSTRUMENTATION, INC., UNI-VENT MODEL 750M PORTABLE, SELF-CONTAINED VENTILATION SYSTEM

- IMPACT INSTRUMENTAION, INC., MODEL 754/754M PORTABLE, SELF-CONTAINED VENTILATION SYSTEM

- OMNI-TECH MEDICAL, INC. OMNI-VENT, SERIES D MRI VENTILATOR

Product and Manufacturer

BIRD PRODUCTS, CORP. BIRD AVIAN PORTABLE VENTILATOR (MILITARY VERSION) MODEL 15300



Bird Products Corporation
1100 Bird Center Drive,
Palm Springs, CA 92262
Telephone (619) 779-7200
(800) 328-4139

Date Evaluated: April 1994

Description:

The Bird Avian Portable Ventilator, Model 15300 is a portable, electronically controlled, time or volume-cycled, pressure-limited ventilator. It can support a variety of ventilation modes: CONTROL, ASSIST/CONTROL and SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION (SIMV). The Bird Avian is microprocessor controlled and provides the operator with a variety of controls and comprehensive alarms including: Automatic apnea backup ventilation, 0-100 Liter Per Minute (LPM) peak flow, 0-150 Breath Per Minute (BPM), 10-100 cm H_20 peak inspiratory pressure, Proximal airway pressure monitoring, and Audio/Visual alarms for High/Low peak pressures, apnea, inverse inspiratory/expiratory (I:E) ratio, and patient circuit disconnect.

Summary:

The Bird Avian Portable Ventilator, Model 15300 is considered CONDITIONAL for use inflight on USAF large-bodied cargo aircraft only. The following recommendations apply:

1. A heat-moisture exchanger should be used for maintaining airway humidification.

2. Respiratory technician is required to monitor tidal volume while inflight to adjust unit appropriately.

3. The Bird Avian Portable Ventilator, Model 15300 is to be operated on battery power for take-off and landings.

Power Requirements:

The Bird Avian has its own internal rechargeable battery, 115/230 VAC, 50-400 Hz multivoltage switch selectable AC power supply and 12 VDC power cable to allow for connection to external 11-30 VDC positive or negative ground power sources. The battery pack may be recharged within the range of the aforementioned AC or DC voltages. The Bird Avian operates from gas sources capable of delivering 40-60 PSIG. These include compressed gas cylinders (air, oxygen, or air/oxygen mixtures), medical grade air compressors, and PTLOX or onboard aircraft gas

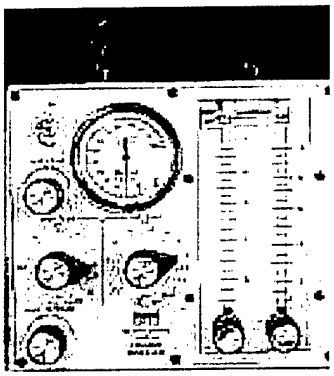
sources. The Bird Avian can also accept blended gas mixtures from a gas blender. Positive End Expiratory Pressure (PEEP) may be used in all modes of operation.

Procurement: Manufacturer

Reference: Technical Report number: AL/CF-TR-1995-0060

Product and Manufacturer

BIO-MED DEVICES MVP-10 NEONATAL/PEDIATRIC VENTILATOR



International Biomedical, Inc.
8508 Cross Park Drive
Austin, TX 78754-4557
Telephone (512) 873-0033

Date Evaluated: October 1999

Description:

The Bio-Med Devices MVP-10 Neonatal/Pediatric Ventilator was certified in April 1990 as a component of the International Biomedical Neonatal Transport System. The ventilator, designed specifically for neonatal use, is difficult to operate at altitude because the ventilator parameters require constant monitoring and frequent adjustments. Controls, that require adjustment in response to altitude changes, are inspiratory time, expiratory time and pressure. In most cases, it is recommended that an approved oxygen/air blender be used to deliver the required gas mixture to the patient. In some cases, for gas conservation, when used on the C-21 aircraft, it may be more beneficial to NOT use a blender, but to connect the gas lines directly to the ventilator. In either case, the decision will be made by the neonatology team member operating the ventilator. It is strongly recommended that an approved oxygen monitor be used inline with the ventilator breathing circuit to measure the percentage of inspired oxygen. It is recommended that breathing circuits specifically designed by Bio-Med Devices be used with the MVP-10. During rapid decompression testing from 10,000 to 40,000 ft, the internal valves became inoperable. They resumed operation when altitude was restored to 16,000 ft. Due to this operational limitation, the MVP-10 is approved for aeromedical use, only if accompanied by a neonatology team member who would be available to manually ventilate the infant, if required. May be used only as a component of the Neonatal Transport System, and operated by a trained neonatology team member.

Summary

The ventilator is considered to be CONDITIONAL for aeromedical use as a component of the NTS or secured to the patient's litter. It requires constant monitoring and adjustments during altitude changes. It is approved for aeromedical use, only if operated by a neonatology team member or respiratory therapist.

Power Requirements 50 psi gas source

Procurement: Manufacturer

Reference: USAFSAM-TR-90-23

Product and Manufacturer

IMPACT INSTRUMENTAION, INC., UNI-VENT MODEL 750M PORTABLE, SELF-CONTAINED VENTILATION SYSTEM

IMPACT Instrumentation, Inc.
P.O. Box 508
West Caldwell, NJ 07006
Telephone (201) 882-1212

Date Evaluated: November 1994

Description:

The IMPACT Instrumentation, INC., Model 750M ventilator is a portable, electronically controlled, time-cycled, pressure-limited ventilator. It is controlled by an onboard microprocessor that continuously monitors the patient's airway pressure, all control settings, alarm parameters and power signals. The Impact 750M can deliver gas from a compressed gas cylinder, oxygen blender, electric compressor, PTLOX or onboard aircraft generated oxygen source. Acceptable input gas pressures to the control module may range up to 100 psi, however, FLOW ADJUST control labeling is based on a 50 psi input. The Impact 750M does not consume gas for operating power. It can provide ventilatory support in CONTROL, ASSIST-CONTROL AND SYNCHRONIZED INTERMITTNET MANDATORY VENTILATION (SIMV) modes. Each mode is operable with or without sigh or PEEP. Multiple alarm systems are included.

Summary:

AFMEDF found the IMPACT Instrumentation, INC., Model 750 M ventilator to be CONDITIONAL for use only on C-9A, C-141, and C-130 aircraft. Restrictions for use on USAF large-bodied cargo aircraft: For take-off and landing, operate the unit on battery power. During other phases of flight the ventilator me be operated on 60 Hz or 400 Hz power. Notify the pilot and crew that the equipment is in use.

Power Requirements:

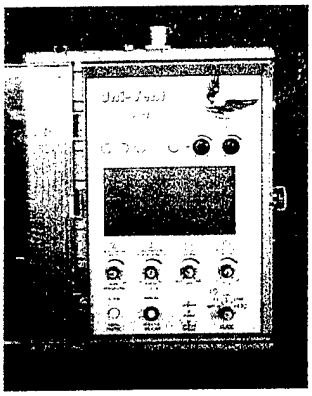
The IMPACT 750M is operable from internal, rechargeable batteries: 11-30 volts AC or DC, positive or negative ground, 50 to 400 Hz. Its battery pack may be recharged within the range of either of the aforementioned AC or DC voltages. A 115/230 VAC, 50-400 Hz Multi-voltage AC power supply and 12 VDC power cable are provided.

Procurement: Manufacturer

Reference: Technical Report number: AL/CF-TR-1994-0112

Product and Manufacturer

IMPACT INSTRUMENTAION, INC., MODEL 754/754M PORTABLE, SELF-CONTAINED VENTILATION SYSTEM



IMPACT Instrumentation, Inc.
P.O. Box 508
West Caldwell, NJ 07006
Telephone (201) 882-1212

Date Evaluated: February 2000

Description:

The IMPACT Instrumentation, INC., Model 754/754M ventilator a portable, electronically controlled ventilator with an integral compressor and air/oxygen mixer. It's microprocessor controls functions, displays airway pressure, alarm parameters, gas source(s) & flows, gas blending and power signals. Assist Control, Spontaneous Intermittent Mandatory Ventilation, and Continuous Positive Airway Pressure modes can be operated with or without Positive End Expiratory Pressure (PEEP) and with or without mandatory ventilations. All modes are PEEP and altitude compensated to minimize patients breathing effort. The Impact ventilator can mix and deliver blended gases from 21-100% oxygen using internal or external source(s). The unit weighs approximately 13 lbs. Its dimensions are 8.87 inches W. X 11.5 inches H. X 4.5 inches D. The power supply is 1.88 inches W. X 2.75 inches H. X 8.5 inches D. and weighs 4.16 lbs.

Summary:

AFMEDF found the IMPACT Instrumentation, INC., Model 754/754M ventilator to be ACCEPTABLE for use on all U.S. Air Force aeromedical evacuation aircraft while operating form 115 VAC/60 & 400 Hz, 28 VDC, and internal battery power.

Power Requirements:

The unit operates using 115 VAC/60 & 400 Hz, 28 VDC, and internal rechargeable battery.

Procurement: Manufacturer

Reference: Technical Report number: AFRL-HE-BR-TR-2000-0013

Product and Manufacturer

OMNI-TECH MEDICAL, INC. OMNI-VENT, SERIES D MRI VENTILATOR

Omni-Tech, Medical, Inc.
6206 SW Ninth Terrace
Topeka, KS 66615

Telephone: (913) 273-8915

Date Evaluated: May 1995

Description:

The Omni-Vent is a pneumatically powered, single circuit, volume-constant, time-cycled and flow-variable ventilator. This ventilator utilizes a high-pressure drive with high internal resistance to control pressure and is considered a non-constant pressure generator. As such, it produces a flow pattern that is constant in spite of changes in lung mechanics (inspiratory square wave). The Omni-Vent has quick-connect features that allow the operator to provide for all clinical ventilatory needs: controlled ventilation (CV), continuous-flow intermittent mandatory ventilation (IMV), constant positive airway pressure (CPAP), high-frequency and jet-ventilation, Positive and expiratory pressure (PEEP), and inspiratory to expiratory ratios that are infinitely adjustable to inverse proportions if needed. A pressure-relief valve allows for both the prevention of barotrauma and time-cycled, pressure-relieved ventilation.

Summary:

The Omni-Vent Series D passed essential laboratory and inflight testing. It is considered CONDITIONAL for use on aeromedical evacuation missions. A respiratory technician or medical attendant is required to monitor tidal volume and adjust unit appropriately during all phase of flight. For identification of an approved Omni-Vent Series D MRI Ventilator, we require the letters AE be printed after the serial number, e.g., Serial No. 3173AE. Note: Omni-Vent requires the custom Omni-Vent disposable tubing circuit, or any circuit where the Bird No. 2575 exhalation value is used since these are the only circuits that will function properly.

Power Requirements: Gas Powered 25-140 psi (Medical Grade air or oxygen)

Procurement: Manufacturer

Reference: Technical Report number: AL/CF-TR-1995-0072